A COMPOSITE RESIN VERSUS AN AMALGAM: A STUDY OF CERTAIN PROPERTIES AND THE DESIGN AND INITIATION OF A CLINICAL INVESTIGATION

by

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INTRODUCTION

Before the turn of this century some rather ambitious though sometimes crude efforts were aimed at developing the ideal filling material. Fletcher[1] in 1890 presented a review of some twenty years of his life which had been devoted to such efforts. After many attempts he finally developed a cement that met all of the in vitro criteria he had established, and yet the material totally failed in the oral environment. He reported that:

> ... this failure permanently disheartened me. ... I acknowledge myself fairly beaten, whilst apparently on the verge of success; but there is no reason why others should not succeed where I failed. The failure of one, or three, or a score of experimenters, is no proof that the required material does not exist; it simply proves that the search is not an easy one.

Indeed the search is most difficult and scores upon scores of investigators have participated since then but all of the secrets are yet to be uncovered. Fletcher's dramatic story serves as a testimonial to the fact that in vitro testing, although necessary for screening materials, occasionally yields results that are inconsistent with the in vivo performance of a material.

In 1951 Harris[2] predicted that the perfect filling material, when discovered, would be an organic plastic. Research efforts have not yet proven him wrong and perhaps future research will verify his prediction.

Silver amalgam is a popular and acceptable posterior restorative material. Its high thermal conductivity and unesthetic properties are tolerated for lack of a more practical material; however, in obvious anterior regions of the mouth its use is contraindicated. Unfilled, self-curing acrylic resins have become very popular for esthetic restorations in anterior teeth but this material's inherent low strength, low modulus of elasticity, and low abrasion resistance limit its use to non-stress bearing areas.[3]

It would be desirable for the dentist to have available an esthetic restorative material with sufficient durability and dimensional stability to adequately restore posterior cavity preparations as well as anterior ones. A relatively new composite resin restorative material (ADAPTIC Brand Anterior/Posterior Dental Restorative) was developed with that thought in mind.

Silver amalgam is undoubtedly the most practical and most frequently used filling material presently available for Class II restorations. Nadal, Phillips, and Swartz[4,5] have demonstrated the inherent ability of silver amalgam to succeed as a Class II restoration even under less than optimum conditions. It follows, then, that silver amalgam is an excellent material to use as a control for laboratory and clinical tests which are designed to evaluate certain properties of the new composite resin restorative material, as well as its clinical performance in Class II restorations.

Therefore, the purpose of this investigation was to make such an evaluation.

REVIEW OF LITERATURE

Development of the Composite Resin Restorative Materials

Composite resins are the newest type of commercial restorative resins. The resin matrix of most of these materials is the reaction product of an ether of bisphenol-A and acrylic monomers which results in a molecule with an epoxy axis and acrylic reactive end groups. The reactions of the end groups are then responsible for the polymerization of the resin; the reactions are initiated and catalyzed by the conventional benzoyl peroxide-amine system.[6]

Other resins that have been investigated for possible use as the matrix or organic binder in composite materials include: aziridino polyester, conventional methyl methacrylate, cyanoacrylate, polyamide, polycarbonate, polystyrene, polyurethane, and vinyl co-monomers.[7-12] Of this list, the conventional methyl methacrylate resin is the only one available for commercial use. But many of these materials are not technically considered to be reinforced restorative materials because the addition of fillers does not appreciably improve the properties when compared to the unfilled resin.[7]

In the true composite materials the resin matrix may make up only 20 to 30 per cent (by weight) of the total material and the rest is some inert filler which affords the material improved properties. The filler particles are first surface-coated with vinyl silane and then incorporated into the unpolymerized resin. As polymerization takes place, the coated particles bond to the resin, thereby reinforcing it. The reinforcing agent then becomes the major stress-bearing component.

Various filler particles have been tested and some are available in different commercial preparations. These include aluminum oxide, apatites, ceramic powder, fiber glass, glass beads and rods, lithium aluminum silicate, quartz, titanium dioxide, and tricalcium phosphate.[6,7,12,13]

Bowen[14-16] first suggested that these materials might have dental application some 15 years ago. Early reports of his work with the resin binder and fine particles of fused silicon dioxide implied that dentistry was on the verge of having a nearly perfect filling material, but he indicated that more detailed investigation was needed before any definite conclusions could be drawn.

In 1962 Sahs, Simon, and Wick[17] reported on some preliminary work with isolated anorganic enamel particles reconstituted with plastisols as a filler. Both methyl methacrylate and epoxy resins were tested as a matrix. But to obtain an acceptable setting time for the experimental materials the filler content had to be reduced to such a level that other desirable properties were sacrificed.

Soon after this Bowen[18] incorporated in his resin formulation irregularly shaped vinyl silane-coated silica particles having dimensions of approximately 150 microns or less. This reinforcement improved the physical properties considerably over those obtained with unreinforced direct filling resins. In another publication,[19] he reported that the physical properties of the material could be further improved by controlling the shape and size of the reinforcement particles. He was able to increase the reinforcement-to-resin ratio by replacing the irregularly shaped particles with two different sizes of spherical particles. Thus only 14 per cent resin was needed as a binder for the particles, this was 12 to 16 per cent less than in earlier formulations. This modification reduced the polymerization shrinkage and resulted in modulus of elasticity and thermal expansion values nearer to those reported for human tooth structure.

As the research with composite resins continued, a combination of glass beads and rods as reinforcing agents offered certain additional advantages, according to Chang, Dahlman, and Rueb.[20] The translucent beads and rods provided good color matching to the surrounding tooth structure. The combination of beads and rods also produced a smoother surface than beads alone, which seemed to reduce staining and improve wear resistance of the material.

Lithium aluminum silicate (beta eucryptite), a synthetic mineral, attracted some attention as another possible reinforcing filler. Bowen[21] reported that it is most unusual since it has a negative coefficient of thermal expansion at normal temperatures. It is also clear, colorless, and has an acceptable refractive index. He warned that the surface alkalis must be removed from the particles to obtain optimum silane coating. Boyd, Colin, and Kaufman[22] tested a composite material using 200 mesh beta eucryptite particles as the reinforcing agent. Based on tests of tensile strength, hardness, and long term water sorption they concluded that the particles required 12 to 16 monomolecular layers of silane coverage for best results.

A relatively new system described by Patrick, Kaplan, and Beaver[23] is unique in design since it requires a silane cavity liner followed by application of a rubbery polymer interliner before placing the glass reinforced resin restorative material. Preliminary data are encouraging with respect to the bond strength developed at the interface of the cut tooth surface and the three-part restoration.

In 1967 Bowen and Argentar[24] introduced newly synthesized dimethacrylate monomers suitable for evaluation as the organic binder in composite materials. Better color stability was at least one improvement expected from this new resin compared to the earlier resin formulation. A recent and more detailed report by Bowen and Barton[25] suggests that in addition to the promising dimethacrylate monomers, newly developed accelerators, adhesion-promoting coupling agents, reinforcing fillers, and stabilizers will lead to an improved "second generation" of composite filling materials.

Physical and Mechanical Properties

"Development of the new and improvement of the old - these are two earmarks of advancement in the field of dental materials," according to Stanford.[26] The advancement in material science usually centers around the improved physical and mechanical capabilities of the materials being evaluated. Of course, in dealing with dental materials, one must also be mindful of the reaction of living tissue to these materials. Any commercially available material has passed certain minimum requirements concerning its compatibility with living tissue and has been declared biologically safe if used in the prescribed manner. Thus a practicing dentist, using commercial materials, should select them by choosing those with the most desirable physical properties for the areas in which they are designed to be used.[27]

Bowen and Rodriquez[28] measured tensile strength of a number of dental materials. They found that the average tensile strengths of one zinc phosphate cement and four different silicate cements were relatively low, but the average tensile strengths of two different conventional direct filling resins ranged from 4000 to 5000 pounds per square inch. They also measured the tensile strengths of human and bovine dentin and enamel samples and found human dentin to be 5800 and human enamel 1200 pounds per square inch. Two experimental resins were also evaluated in this study. One material had vinyl silane surface treated fused silica particles as a filler, which was combined with conventional methyl methacrylate resin for the organic binder; this material exhibited a tensile strength of 4000 pounds per square inch. The other experimental material was a combination of the treated silica filler with 30 per cent binder which was an adduct of glycidyl methacrylate and bisphenol-A; this composite yielded a tensile strength of 5000 pounds per square inch. These investigators later reported the tensile strength of human dentin to be in the range of 7500 pounds per square inch.[29] The best results obtained from the experimental composite resins showed tensile strengths about one-half those of human dentin and three times those of enamel. They also demonstrated that the silane surface treatment of the silica powder was significantly related to the tensile strength of the material.

Addent was the first commercially available composite restorative resin and consequently it received considerable attention when it was introduced to the profession. In 1966 Hollenback, Villanyi, and Shell[30] contributed a comprehensive report on the physical properties of Addent anterior and posterior materials. Their investigation included the ability of the materials to receive a polish, abrasion resistance, adhesion, compressive, transverse and tensile strengths, dimensional change during polymerization, flow, and hardness. Although none of the properties tested on these materials would indicate that they are unacceptable for clinical use, outstanding values were recorded for abrasion resistance, hardness, and strength. The Addent materials showed considerably more resistance to abrasion than silicate cement and unfilled acrylic resin. The Knoop hardness number for the anterior material was 45 and for the posterior material 58. Both materials developed compressive strengths in the range of 27,000 to 30,000 pounds per square inch after two weeks, besides showing relatively high 15 and 30 minute strengths. After one week tensile strengths averaged in the range of 5100 and 5700 pounds per square inch while transverse strengths were close to 6600 pounds per square inch. The investigators concluded that Addent represented progress in the development of new dental restorative materials.

Test specimens of amalgam, silicate cement, conventional self-curing resin, the commercial composite resin, a proposed anterior composite material, an experimental polyurethane composite, and ivory were tested for abrasion resistance by Buonocore, Matsui, and Yamaki.[31] The specimens were tested under identical conditions in a tooth brushing machine using matched nylon bristle toothbrushes and mixtures of toothpaste, pumice, and water; toothpaste and water; and water alone. All materials showed considerable wear when brushed with the pumice-toothpaste slurry, and comparatively less wear in the toothpaste slurry. Wear of all specimens brushed in water alone was negligible. In abrasion resistance, the commercial composite and the experimental material were comparable to amalgam and silicate cement. The authors concluded that the wear observed under the test conditions probably would not be duplicated in vivo for many years. This conclusion was based on their clinical observations of conventional and experimental Class V resin restorations in patients known to brush their teeth at least twice a day. These clinical restorations had shown no significant evidence of wear after three years.

Peterson, Phillips, and Swartz[32] compared four commercial resins (Addent, Bonfil, Mer-Don 7, and Sevriton) with regard to the following properties: abrasion resistance, color stability, hardness, marginal adaptation, relative adhesion to tooth structure, resistance to stain, solubility, water sorption, and yield point under compression. No single resin was superior to all others in every respect, although Addent was appreciably harder and more resistant to abrasive materials than the others and the yield point of Addent was more than twice that of the other resins. The solubility of all test materials was negligible in water. Ultra violet light exposure did evoke a perceptible change in the color of Addent and it was more susceptible to stain from methylene blue and lipstick than the others; however, cobalt sulfide stained Sevriton and Bonfil. Sevriton showed better adhesion to dentin than the others. Marginal leakage tended to increase slightly with all materials as they aged and the leakage was also more pronounced under conditions of thermal change. Water sorption of Addent was considerably slower but continued for a much longer period; ittook 200 days for Addent to reach the 25 day maximum sorption levels of the other resins, and yet Addent never seemed to reach equilibrium under the test conditions.

In 1968 Buonocore[33] submitted data concerning some properties of two commercial composites, Addent and Dakor. He considered these materials as contact adhesives which unfortunately lose their adhesive qualities after contact with the oral environment. He pointed out that both materials are very resistant to oral dissolution. Dakor exhibited better color stability than Addent when exposed to ultra-violet light, but the author noted that the significance of this test had not been correlated with in vivo conditions. The compressive strength of both materials was comparable and in the range of 20,000 pounds per square inch. Both materials proved to be brittle, as indicated by the clean fractures of the strength specimens. Tensile strength and hardness values were somewhat greater with Addent. Water sorption data were about equal but Dakor reached equilibrium much sooner.

In another study of resins Custer[34] evaluated some properties of four commercial resins: the composite Addent; a conventional resin which also has a filler added, Chameleon; and two unfilled conventional resins, Bonfil and Sevriton. Of these materials, Addent again exhibited the least color stability. Addent and Chameleon had the best resistance to abrasion. After thermal cycling, these same materials showed the best resistance to marginal staining and the least evidence of marginal stress. They also had superior tensile strength (Addent 4200 psi and Chameleon 3920 psi). The hardness of Addent was shown to be superior. Custer concluded that at least in a non-clinical evaluation, the physical properties of resin materials improve when inorganic fillers are incorporated in them.

Certain physical and mechanical properties of four commercial resin materials (Addent 12, Addent 35, Dakor and Sevriton) were also measured by Macchi and Craig.[35] In addition to reporting on several properties which correlated with previous works, they demonstrated that polishing procedures actually roughened the surface of composite resins. They also showed that the composite materials were more dimensionally stable during polymerization as well as during thermal change. It was interesting to find that one composite (Addent 12) compared favorably to the unfilled resin (Sevriton) with respect to its modulus of resilience.

Recently Lee, Swartz, and Smith[36] have employed many laboratory tests to add to the already accumulating data concerning the properties of the composite resin materials. The four commercial composites were: Addent 12, Addent 35, Dakor, and a relatively new material, Adaptic. These materials are described as similar resin systems but variations occur as to the nature and quantity of the formulating ingredients. The inert filler is the ingredient primarily responsible for the property variations found in these materials. The fillers may differ in composition, distribution, purity, shape, and size.

For all 15 properties tested in this study, Adaptic was found to be superior to the other materials in varying degrees. Generally Dakor was inferior. The authors of this report suggested that Adaptic might be suitable for both anterior and posterior restorations in accordance with the manufacturer's claim.

Lee and Swartz[37] carried out additional studies of the same four composite materials. Surface characteristics and marginal adaptation were evaluated with a scanning electron microscope. They found that the two materials that contained irregularly shaped filler particles (Adaptic and Addent 12) yielded smoother surfaces after sanding or if cured against a matrix.

The studies point out that significant improvements of certain properties have been realized with the advent of composite resin systems for esthetic restorations.

Marginal Leakage. The first reports of marginal leakage involving a composite resin restorative were contributed by Going and Loiselle.[38] In 1965 they submitted some preliminary work using radioisotopes to detect leakage of Addent restorations. The study included an investigation of: (1) leakage around restorations with no cavity liner, cavity liner applied to dentin, and cavity liner applied to dentin and enamel margins; (2) leakage around restorations which were subjected to hot and cold temperature variations; and (3) the permeability of the dentin coated with "3M Cavity Liner" as compared to dentin coated with a copal resin varnish. The results of this study indicated that "... 3M Brand Addent may have potential as a restorative material."

A somewhat similar study by Wakely and Hoffman[39] revealed that Addent restorations placed in conjunction with the liner leaked less than those placed without a liner. The leakage of both categories increased after the specimens were subjected to extreme temperature changes.

The original work of Going and Loiselle[38] was later expanded by Going and Sawinski.[40] Their comparative study included work with conventional acrylic resins, gold foil, silicates, and silver amalgam in addition to the composite material. They showed that the composite material provided at least as good an initial seal as any other material tested, except gold foil. The initial seals of silicate and gold foil restorations seemed to remain relatively unaffected even after they had endured extreme temperature variation, whereas the composite material demonstrated a slight increase in its leakage pattern due to the temperature changes. Amalgam seals improved with time and the composite maintained its good seal up to eight weeks storage in incubated saliva.

A unique technic developed by Going, Myers, and Prussin[41] enabled them to study microleakage around filled and unfilled resin and silicate cement restorations in vivo and to compare these results with similar in vitro tests. The results correlated with previous leakage data but in general the in vivo leakage was greater than in vitro leakage.

Guzman, Swartz, and Phillips[42] carried out a detailed investigation of marginal leakage of certain restorations subjected to thermal changes. Silver amalgam and a composite resin were among the materials tested. Amalgam restorations placed without the use of cavity varnish showed the most leakage of all restorations placed but the amalgam restorations placed with cavity varnish had the least leakage. The composite resin restorations maintained good seals even after three months of storage and 500 thermal cycles.

A technic of grading the amount of penetration of basic fuchsin dye around restorations was employed by Tani, and Buonocore[43] to assess the sealing capabilities of several commercial anterior restorative materials. Design and depth of cavity preparations, pin retention, storage time and temperature cycling were variables introduced in the study for evaluation as well as the different materials used. Of the materials tested, Dakor and Sevriton showed the best leakage patterns after 24-hour immersion. The leakage of Addent specimens seemed to improve slightly after storage in water for three months. Dakor and Sevriton seals remained good. But after three months storage in water the silicate cements and Bonfil specimens showed maximum leakage. All materials tested, except silicate, exhibited maximum leakage after being subjected to temperature cycling between 4° C. and 60° C. The depth of cavity preparations seemed to be irrelevant. The amount of leakage around bowl, flowerpot, and ink-well shaped cavities with or without pins was observed to be greater than around standard Class V preparations.

In addition to reporting on surface characteristics of four composite resin materials which were mentioned earlier in this review, Lee and Swartz[37] evaluated leakage and adaptation of the materials by the combined use of the scanning electron microscope and radioisotope studies. They also included amalgam, silicate cement, and unfilled poly (methyl methacrylate) in order to make additional comparisons with the composite materials. The scanning electron microscope allowed the investigators to visually examine how well the various materials adapted to the cavity walls and to the cavity floors at high magnifications. The "gaps" between the tooth structure and the filling materials could be measured. All specimens showing isotope leakage also exhibited gaps; however, the size of the gaps did not correlate with the isotope data. Sometimes specimens with relatively large gaps between tooth structure and the restoration exhibited little or no isotope penetration and vice versa. Except for amalgam, the cavity adaptation correlated to the volumetric polymerization shrinkage of the materials. Although thermal cycled specimens showed increased gap size and isotope leakage, this increase was not proportional to the thermal coefficient of expansion of the materials. The authors therefore stated that polymerization shrinkage seems to have a greater bearing on adaptation than the dimensional change induced by temperature change. They observed that one composite resin (Adaptic) exhibited closer marginal adaptation and cavity adaptation, as well as less isotope leakage, than all other materials tested, including amalgam.

<u>Clinical Evaluation</u>. The dental literature is nearly devoid of well controlled, long-term clinical comparative studies of dental restorative materials. Because of the relative newness of composite restorative materials, there is even less clinical substantiation for these systems. There is a real need for more of this type of research.

In 1955, about the time that the composite materials were in the embryonic stages, Hedegard[44] designed a workable plan for in vivo evaluation of three conventional direct filling resins and a silicate cement. The clinical comparisons made use of both a visual and a microscopic (x50) examination performed concurrently in the same light. Eight descriptive criteria (four visual and four microscopic criteria) ranging from good to bad were set down to facilitate and standardize the grading of each restoration. The purpose of the study was to evaluate marginal accuracy and the ability of the materials to maintain their integrity over a three year period.

Ten years later Schulman[45] reported a clinical testing program designed to compare the performance of the new composite restorative system, Addent, with silicate cement and conventional acrylic resins in Class III and Class V restorations. Adjacent cavities were restored so that comparisons could be made in the same oral environment. Examinations of the different restorations were made one month, three months, and six months after placement. The author concluded that Addent offered promise for a more permanent type of esthetic restoration for Class III and Class V cavities then either silicate cement or conventional acrylic resin restorations.

In the same year Ryge[46] re-emphasized the need for clinical evaluation of dental restorative materials. He pointed out that there was no generally accepted method for accurately determining the clinical behavior of materials. Thus the practicing dentist had to choose materials for clinical use with little scientific evidence. Ryge then described his methodical design for clinical evaluation of restorations, which has been proven reliable.

Johnson and his co-workers[47] carried out a clinical evaluation and comparison of a silicate cement with two composite resins when placed in contralaterally paired or adjacent Class III and Class V restorations. Ninety-eight restorations were placed by one operator and 91 were graded for color match, cavo-surface marginal discoloration, dark deep discoloration, contour, and marginal integrity after one year. Two examiners, specifically trained in the evaluation procedures, rated the restorations independently. Statistical analysis of the data revealed that a significantly higher number of silicate restorations had loss of contour and marginal deterioration than either of the composite resins tested.

In a similar study designed for posterior restorations, McCune et al[48] placed and rated amalgam, silicophosphate cement, and composite resin restorations. A total of 202 restorations were placed by one operator. After one year, 181 restorations were evaluated for surface characteristics, anatomic form, and adaptation by two examiners independently. The only significant difference found was that the silicophosphate cements and the composite material showed better adaptation (less marginal breakdown) than the amalgam.

In another clinical study by Bowen, Paffenbarger, and Mullineaux,[49] 74 silicate cement restorations and 24 direct filling resin and reinforced resin restorations were placed, with few exceptions, on proximal surfaces of anterior adjacent teeth. The restorations were evaluated clinically for extended periods. The conventional resins and the reinforced resins exhibited better surface contour than the silicates, but there was little if any difference in contour between the two resinous materials. Marginal integrity of the resins also proved much superior over the years of investigation. After three and one-half to six and one-half years of service, 42 per cent of the silicates needed replacement but only 4 per cent of the resins needed replacement after four to five years of service.

McCune, Cvar, and Ryge[50] recently reported three-year results of two studies already cited.[47,48] In the study of anterior restorations the relative superiority of the resin materials was maintained for contour and marginal integrity. However, in the study on posterior restorations only one silicophosphate cement maintained superiority for marginal adaptation. The other cement and the composite resin lost their superior ratings for that characteristic. The surface characteristics of the silicophosphate cements were better than those of the resins or the amalgams and the amalgam restorations proved to have the best anatomic form.

A new experimental material referred to as TD 71 by McLean and Short[51] may also have a clinical potential. This new material is a methacrylate resin reinforced with coated ceramic particles between two and 75 microns. They believe that this material has a very strong bond between its inorganic phase and the resin matrix. The one-year results of a clinical study of this material as Class III and Class V restorations were encouraging. It was reported that the esthetics of the restorations after one year were of a particularly high order.

METHODS AND MATERIALS

The aim of this project is to compare a new composite resin restorative material with amalgam as a Class II restorative in clinical situations. Considerable laboratory data on the physical and mechanical properties of the two materials were collected to complement the clinical study. It was hoped that the laboratory data will lead to a better understanding of the long-term clinical behavior of the two materials.

The new restorative materials which were studied are commercially available. Adaptic[a] is a composite resin restorative material, 78 per cent of which is an inorganic filler of irregularly shaped particles of vinyl silane-treated alpha-quartz.[52] For this study Adaptic was considered the experimental material. Velvalloy,[b] a new fine cut amalgam alloy,[53] was the control material. The manufacturers' directions were followed for manipulation of the materials.

PART I - LABORATORY STUDY

The amalgam specimens were made from identical mixes using Velvalloy pellets and the correct amount of mercury dispensed[c] to give a mercury/alloy ratio of 1.1:1. The proportioned metals were then triturated to a uniform mix in a high-speed oscillating amalgamator.[d]

Most of the Adaptic specimens for the laboratory tests were mixed at a Universal paste/Catalyst paste ratio of 1:1 (± 0.1 mg.) as

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a Johnson & Johnson, New Brunswick, N.J.
b S. S. White Dental Mfg. Co., Philadelphia, Pa.
c S. S. White Mercury Dispenser 69A, S.S.White Dental Mfg. Co., Philadelphia, Pa.
d Wig-L-Bug, Cresent Dental Mfg. Co., Chicago, Ill.

determined on an analytical balance. A few specimens were mixed at different ratios for reasons which will be explained when the test procedure is described.

Some of the properties investigated were not applicable to both materials. Mercury content of the laboratory amalgam specimens was determined but obviously this was unnecessary for the composite resin specimens. Similarly, there was no need to evaluate color stability, stain resistance, solubility, or water sorption on the amalgam material. However, abrasive resistance, hardness, marginal leakage, and strength data were collected on both materials for comparative purposes.

A. Abrasion Resistance

Split stainless steel molds were used to make four cylindrical test specimens of each material. The specimens were 12 millimeters long and six millimeters in diameter. They were stored in distilled water for 24 hours.

The specimens were tested for their abrasion resistance with a motor-driven toothbrushing machine. They were uniformly mounted in slurry pans and stabilized, securely in position, by base plate wax. The slurry pans were then properly positioned on the toothbrushing machine and the abrasive slurries consisting of 10 grams of flour of pumice and 20 ml. of distilled water, were added. Each specimen was brushed in this identical manner for one hour (9000 strokes).

Earlier data[54] on these same two materials tested under the same conditions using a calcium carbonate slurry as the abrasive showed very little wear on either material. In addition, no differences could be detected between the two materials with respect to abrasion resistant properties. Therefore the more abrasive slurry of flour of pumice and distilled water was chosen for this test, in an attempt to more clearly define the ability of these materials to resist abrasion.

Before the testing period, the specimens were surface dried and weighed using standardized procedures to ± 0.1 milligram. After the testing period the specimens were carefully removed from the slurry pans and cleaned in a like manner. They were then placed in distilled water for one hour before their final weights were determined.

A second method was also used for obtaining a record in order to illustrate the amount of wear on the specimens from this test. Shadowgraph silhouettes using a standardized photographic technic were made to show the appearance of the specimens before and after they were subjected to the abrasion tests. The specimens were thus evaluated by the percentage of weight loss and by visual comparison of the shadowgraph silhouettes. Comparative data for resistance to abrasion between the two materials were derived.

B. Hardness

Surface hardness of the two test materials was measured with a Knoop diamond indenter in a Tukon testing machine equipped with a calibrated microscope. Flat discs of each material were tested at intervals of 15 minutes, one hour, and 24 hours after mixing. The discs were stored in air at room temperature during the testing intervals.

Since all indentations should be approximately the same size when comparative data are being collected with this test, it was necessary to vary the load on the indenter. For the 15-minute Velvalloy specimens a 100 gram load was used; for one-hour Velvalloy data a 200 gram load; and for the 24-hour measurements, a 300 gram load. All Adaptic specimens were evaluated with a 400 gram load. In all tests the identation period was 20 seconds.

C. Marginal Leakage

The relative ability of the two test materials to seal cavity preparations was evaluated by the established technic which has been described in detail in several research reports from Indiana University School of Dentistry, Department of Dental Materials.[55-58] The technic uses sound, extracted human cuspids and bicuspids which have never been allowed to dehydrate (stored in tap water). Class V cavity preparations are cut in the teeth and subsequently restored with the desired material. After the desired testing variables and/or storage times for each test group have been accomplished, the depth of marginal penetration permitted by the individual restorations can easily be traced by immersing the teeth in a Ca^{45} radioisotope solution. The depth of marginal penetration of the isotope can then be seen on an autoradiograph which results from exposing ultra-fast dental x-ray film to the specimen.

A total of 114 test restorations, in four separate test groups, were placed and evaluated in this phase of the study. At least 11 Class V Adaptic restorations and 11 Class V Velvalloy restorations were evaluated for marginal leakage in each test group. The methods of mixing, inserting, and finishing or polishing the restorations simulated the methods used in the clinical part of this investigation, which is discussed in more detail in that section of this report. The preparations which were to be restored with the amalgam were coated with varnish,[a] and the ones restored with the composite resin remained uncoated.

Three of the four test groups evaluated merely involved a difference of storage time. One group was stored in tap water at 37° C. for one week. Another group was stored for one month, and yet another group for three months.

The fourth group was also evaluated one week after the restorations had been placed. However, the specimens in this group were thermocycled in a hot and a cold water bath for 2500 cycles. The specimens were cycled 500 $\pm$ 100 times a day and during a cycle they were immersed alternately in each water bath for 30 seconds. A temperature gradient of at least 40° C. between the baths was maintained with hot tap water continually running through one bath and ice water pumping through the other bath.

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a Copalite, Harry J. Bosworth Co., Chicago, Ill.

After the testing periods, an autoradiograph of each restored tooth was obtained and the marginal leakage allowed by the restorations was assessed. Conclusions could then be drawn about the ability of one material to seal the cavities under the test conditions as compared to the other material.

D. Strength

1. Compressive strength.

Compressive strengths of the two materials were measured at intervals of one hour, 24 hours, one week and one month after the specimens were prepared. In all, 140 cylindrical specimens were fractured under compressive loads. At least 10 specimens of each material were evaluated in each of the four time-interval categories. All specimens were stored in distilled water at 37° C. for the designated period between preparation and testing. For convenience, the Adaptic specimens were prepared in split stainless steel molds which are 12 millimeters long and 6 millimeters in diameter; the Velvalloy specimens were made from a mold 10 millimeters long and 5 millimeters in diameter.

In addition to 22 one-week Adaptic specimens that were tested for compressive strength using the Universal paste/Catalyst paste ratio of 1:1, five specimens were tested at a 2:1 ratio and five others at a 1:2 ratio. This was done to determine if a significant change in the compressive strength of the material would result when the ratio of the two pastes was varied.

The force required to break each specimen was recorded on a Riehle testing machine, using a head speed of 0.035 inch per minute.

2. Tensile strength.

Using the diametral-compression test for tensile strength described by Sweeney and Burns,[59] the tensile strengths of the two materials were evaluated. The type of specimens, the time intervals of testing, and the testing conditions were carried out exactly as for the compressive strength tests already described. The difference between the tests is that the compressive stress is measured when the cylindrical specimens are compressed perpendicular to their long axes. However, in measuring tensile stress the specimens are compressed along their long axes. The tensile stresses developed are directly proportional to the applied load.

A total of 100 specimens were tested for tensile strength. At least eight specimens in each testing category were used. The diametrically applied force to each specimen was developed by the Riehle testing machine using a head speed of 0.035 inch per minute. Phillips et al[60] first used this same equipment when testing various zinc oxide and eugenol cements for tensile strength.

E. Color Stability

The color stability of Adaptic was assessed by a subjective evaluation based on the American Dental Association Specification No. 12 for denture base resins.[61]

Flat discs of the material 20 millimeters in diameter and 3.5 millimeters thick were made from brass molds. Two operators, working independently, each made five specimens for this test. In both groups of five specimens, four were tested and one remained as the control. These separate tests were conducted several months apart.

The prepared specimens were stored in the dark for 24 hours before testing. No color differences could be detected visually among the specimens in either group before the test.

After the storage period the test specimens were placed on a revolving turntable (33 revolutions per minute) and exposed to radiation from a 400 watt sunlamp (S-1 bulb) for 24 hours. During this time the control specimen remained in total darkness.

At the end of the testing period all five specimens were randomly placed on a plain white sheet of paper. The identifying numbers on the specimens were concealed. Seven people, individually, made visual judgments regarding any perceptible color differences in the specimens.

F. Staining Characteristics

These tests were very similar to those that Kafalias[62] described for staining denture base resins, and, later, Peterson[58] for restorative resins.

Identical tests were performed simultaneously on two other commercially available restorative resin materials as well as Adaptic to provide comparative data. The other materials choses for testing were Addent 12,[a] a composite resin, and Sevriton Simplified,[b] an

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a Minnesota Mining and Mfg. Co., St. Paul, Minn.
b Amalgamated Dental Trade Distribution, Ltd., London, England

unfilled resin.

The materials were tested for their susceptibility to three different stains: methylene blue, cobalt sulfide, and lipstick. Two types of surface conditions were evaluated, one when the materials were left with a "glass slab" surface and another when they had a "finished" surface. The ease with which the various stains could be removed with toothbrushing procedures was also studied. Twelve separate test groups were required.

The specimens were similarly prepared between glass plates. Shims 1.2 millimeters thick were used to standardize the thickness of the specimens left with a "glass slab" surface. Shims 1.3 millimeters thick were used for the specimens which were to have a "finished" surface; the 0.1 millimeter additional thickness of these specimens allowed for finishing procedures. There were 102 specimens (90 test and 12 control) prepared for these tests.

It is generally agreed that the best surface clinically obtainable for any resin restorative is the surface left by a matrix strip. The "glass slab" surface used here would correspond to the "matrix strip" finish obtained clinically.

Most often, however, the clinical restoration must be finished and smoothed with instruments to its proper contour. The inherent structural characteristics of a composite material such as Adaptic prevent a highly polished surface, therefore it is better to refer to a "finished" surface when talking about this material. It was not possible to finish the surface of the test specimens with the same instrumentation which would be used for clinical restorations and maintain a flat surface. Since a flat surface was necessary to properly evaluate the test specimens in this laboratory evaluation, an alternative finishing procedure was devised.

After observing variously finished surfaces of Adaptic directly under a dissecting microscope, it was decided that the surface obtained with 400A grit carborundum paper exhibited a surface most similar to that obtained by the clinical finishing procedures. Therefore the "finished" surface used for all the test specimens in this category was the flat surface which was obtained by 20 back-and-forth strokes on the wet (tap water) carborundum paper.

Before the specimens were stained, pre-test color values were recorded for each specimen after it had been stored in the dark for 24 hours. Color values were measured with the Hunter Color and Color Difference Meter, which can detect differences on three color scales. The "Rd" scale measures grayness, the "a" scale measures the red-green range, and the "b" scale measures the blue-yellow range. All specimens were scratched on the back surface so that each one could be identified and placed back on the Hunter instrument in the same position in which the original measurements had been recorded.

1. Methylene blue - Only one surface of each specimen was to be stained so the back and edges of the specimens were covered with soft boxing wax. The specimens were first stored in distilled water for

one hour, then immersed in a 3 per cent solution of methylene blue stain for 20 hours. A few drops of aerosol had been added to the stain in order to reduce surface tension.

After the immersion period the specimens were removed from the stain, the surface dried with tissues, and rinsed in running tap water for 15 minutes. Before the wax coverings were removed, they were stored again in distilled water for one hour. The specimens were then ready for their post-test color measurements.

2. Cobalt sulfide - The specimens were prepared in exactly the same manner as just described up to the staining procedure. They were then immersed in a 20 per cent solution of cobalt chloride for 15 minutes, after which they were transferred to a 20 per cent solution of ammonium sulfide for an additional 15 minutes. A black precipitate of cobalt sulfide was observed to form on the surface of the specimens. The specimens were removed, surface dried, and the procedure repeated, except that they were immersed in the ammonium sulfide for 20 hours.

The specimens were then prepared for the post-test color readings just as the ones that were stained with methylene blue.

3. Lipstick - The staining procedure for these specimens was accomplished by "rubbing in" the lipstick[a] on the exposed surface of each specimen with uniform finger pressure for one minute. The excess lipstick was then wiped away with tissues and the specimens were stored

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a "Love That Red", Revelon, New York, N.Y.

in distilled water for 20 hours.

After the post-test color readings had been accomplished, two of the five specimens from each test group were secured in the tooth-brushing machine (described in the section on abrasion resistance). These specimens were brushed for 15 minutes in a slurry of toothpaste[a] (10 grams) and distilled water (5 milliliters). The amount of stain removed by standardized toothbrushing was evaluated by again making color measurements and by visual comparison with the unbrushed specimens.

All of the control specimens were handled the same as the test specimens except that they were of course not exposed to the various stains. During the time that the test specimens were being stained, the controls were stored in distilled water. Half of the controls were brushed with the toothpaste slurry to be compared to the stained specimens that were also brushed.

G. Solubility

To provide comparative solubility data for Adaptic, Addent 12 and Sevriton Simplified were also included in these tests. The technics used were very similar to those described by Norman, Swartz, and Phillips.[63] The materials were properly proportioned, mixed, and allowed to cure on glass plates. The specimens were approximately 10.5 millimeters in diameter and 1.5 millimeters thick. A

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a Crest, Proctor & Gamble, Cincinnati, Ohio metal washer with an inside diameter of 10.5 millimeters was placed under the glass plate to facilitate making the specimens the proper size. The average surface area of the specimens was approximately 2.3 square centimeters. After forming the materials on the glass plates, a stainless steel wire was inserted into each specimen before it hardened. Thus the specimens could be suspended by the wire in the test solutions. The weights of the specimens in a group were not allowed to vary more than 10 per cent from one another.

1. Water - Glass distilled water was used as one of the test solutions. Three milliliters of 5 per cent thymol was added per two liters of the water in order to prevent bacterial growth.

Four specimens of each material were tested. Each specimen was weighed to an accuracy of 0.1 milligram and then suspended in 25 milliliters of the test solution contained in a tared crucible. The crucibles had also been weighed to an accuracy of 0.1 milligram. The specimens remained suspended in the crucibles of test solution and were stored in a dry oven at 37° C. for 24 hours. At the time each specimen was to be removed it was rinsed with glass distilled water, and the rinsings were captured in the same crucible in which each specimen had been suspended.

The contents of the crucible were then evaporated in a dry oven at 100° C. for 24 hours, and the crucibles were then stored at 200° C. for 48 hours to assure that constant weights were attained.

A crucible containing only 25 milliliters of the test solution served as the control. The differences in the initial weights and the post-test weights of each crucible determined the amount of residue left in each crucible. The differences between the weights of the residue in each test crucible and the residue in the control crucible identified the amount of residue from each specimen which had gone into solution during the testing period.

The specimens were tested for five consecutive days. Fresh test solutions and fresh controls were used daily.

2. Citric Acid - The same procedure just described for determining the solubility of the materials in glass distilled water was used in this test. However, instead of using glass distilled water as the test solution, a buffered solution of 0.001 M citric acid (pH 4.0) was used.

H. Water Sorption

Five flat discs of Adaptic 20 millimeters in diameter and 3.5 millimeters thick were prepared in brass molds.

The specimens were stored in a desiccator and weighed daily until a constant weight to an accuracy of 0.1 milligram was obtained. Then the initial weight was recorded and the specimens were put in separate beakers containing approximately 50 milliliters of glass distilled water at room temperature.

At pre-determined intervals the discs were individually removed from the water, uniformly surface dried, and weighed within one minute. The cumulative increase in specimen weight from one weighing to the next was taken as the weight of water sorbed by the specimen. The water sorption value was then expressed as milligrams of water sorbed per square centimeter of surface area.

Water sorption data of the five specimens were collected for 56 days, and the water in the beakers was changed weekly. The water sorption weights were recorded daily for the first four days, again on the seventh day, ninth day, 14th day, 28th day, and weekly thereafter for the remaining four weeks.

I. Mercury Content

Mercury content was determined on a total of 29 Velvalloy amalgam test specimens. The specimens were representative of all five types that were used throughout this investigation, including the clinical restorations.

Specimens were made, using the identical procedures as described, of the four different sizes and shapes which had been used for the laboratory tests. The fifth type of specimen analyzed was to simulate the restorations which had been placed clinically. A maxillary left first permanent molar dentoform tooth was prepared for a mesio-occlusal amalgam restoration. Then using the technics which simulated the clinical procedure, six Velvalloy restorations were placed and subsequently analyzed for mercury content.

The per cent of mercury by weight was determined for each specimen by the method described by Crawford and Larson.[64] Briefly, this technic involves volatilization of the mercury away from the particles of the crushed amalgam specimen in a nitrogen gas atmosphere. The mercury content is determined by the difference in weight of the particles before and after the volatilization process.

An amalgam sample of known mercury content was analyzed with each test group to serve as a control and verify the technic.

PART II - DESIGN AND INITIATION OF A CLINICAL STUDY

The objective was to conduct the clinical study in such a manner that the data collected could be representative of a private practice situation. However, certain controlling factors were strictly adhered to. These controls were designed to minimize certain variables so that the data resulting from this study would be statistically meaningful.

This study was designed in such a manner that evaluation of the restorations would continue for at least three years. The design was based upon the established methodology of the Materials and Technology Branch, Division of Dental Health, United States Public Health Service, for evaluation of clinical restorations as reported by Ryge.[46,65] The clinical evaluation of the involved teeth and restorations includes (where applicable):

a. Color match
b. Cavo-surface marginal discoloration
c. Anatomic form
d. Marginal adaptation
e. Caries

During the clinical evaluation two trained examiners independently assign a code letter grade of A through D (excellent to poor) or H (if not applicable) to each category listed for each restoration used in the study. These grades provide the raw data for statistical analysis. The criteria that the examiners used for rating the restorations are summarized in Tables I through V.

Before any restorations were placed for this study, procedure guides were developed which outlined the methods of operation to be followed for the clinical operators and the assistants. This was necessary in order to maintain adequate variable control throughout the period required to place the number of restorations needed.

Detailed records for each pair of restorations were maintained on a special form provided by the United States Public Health Service. Another form was provided to make daily reports of batch numbers used and to note variations from the usual procedures which may have occurred. Additional forms for recording the data for the baseline and annual evaluations were also provided. Finally the usual records employed by the School of Dentistry were maintained, including health histories, diagnoses, treatment plans, and services rendered.

The procedural details of this study are provided in the following outline.

I. Clinical Population

A. Restorations

1. There were 124 pairs of Class II restorations placed in permanent, posterior teeth of 73 human subjects.

2. One restoration of each pair was Velvalloy and the other was Adaptic.

3. Each pair of restorations was placed by the same operator during the same patient appointment.

4. The choice of which preparation received which restorative material was determined by an unbiased observer using a random table after both preparations were completed.

5. Any two Class II restorations of the specified materials in permanent teeth in the same mouth and in functional occlusion with the opposing arch qualified as a "pair."

B. Patients

1. The patients were in need of the appropriate restorations.

2. The patients were willing to present themselves for annual evaluation for three years after the restorations were completed.

3. Patients were selected from those seeking dental care at Indiana University School of Dentistry.

II. Dental Restorative Materials

A. S. S. White Velvalloy Pellets
B. Johnson & Johnson Adaptic Brand Anterior/Posterior Dental Restorative
C. Dycal Calcium Hydroxide Composition
D. Copalite Cavity Varnish
E. Mercury

III. Operatory Space

A. Adequate space, operating facilities, and equipment were provided at Indiana University School of Dentistry by the Department of Dental Materials.

B. The same provisions were available for the baseline evaluations.

C. The same provisions will be available for all subsequent evaluations; thus the environment for the evaluation will be identical.

IV. Operating Procedures

A. Cavity Preparation

1. Whenever possible, the principles of conservative cavity design were used.

2. Some restorations replaced old defective restorations and therefore those cavity designs were already dictated to a great extent.

3. A standard set of instruments were used for each preparation; the instruments were the same for both operators.

4. If the cavity depth of any preparation indicated the use of base material, calcium hydroxide was placed.

5. All preparations to be restored with amalgam were first coated with varnish.

B. Material Preparation

1. Velvalloy-handled according to the manufacturer's specifications.

    a. The mercury/alloy ratio was 1.1:1.

    b. The correct amount of mercury was dispensed from the dispenser to mix with two pellets of alloy.

    c. Mixing time was 20 seconds.

    d. If one mix was not sufficient to restore the tooth, then a second separate mix was made.

    e. The amalgam was handled only with squeeze cloths and the appropriate instruments.

2. Adaptic-handled according to the manufacturer's specifications.

    a. Universal Paste/Catalyst paste ratio was approximately 1:1.

    b. Mixing time was 30 seconds.

    c. Material was handled with the appropriate instruments only.

C. Insertion and Carving/or Finishing

1. Velvalloy

   a. Insertion time was no more than 150 seconds.

   b. Moisture contamination was avoided by use of rubber dam.

   c. "Tee" brass matrix bands, contoured and wedged, were used to help form the proximal surfaces of the restorations.

   d. Carving was completed within 15 minutes after the amalgam had been condensed into the cavity. (Based on the American Dental Association Specification No. 1 for alloy for dental amalgam).

   e. Polishing was accomplished for the amalgam restorations at least 24 hours after insertion but always before the baseline evaluation.

2. Adaptic

   a. Insertion time was no more than 90 seconds and was accomplished by condensing the plastic material into the cavity with rubber dental stimulators[a,b] and then lightly burnishing the material with an apple seed burnisher.

   b. Moisture contamination was avoided by use of rubber dam.

   c. Brass matrix bands[c] contoured and wedged were used to help form the proximal surfaces of the restorations.

   d. Finishing with carbide finishing burs[d] and rubber points[e] was accomplished after the material had hardened - four minutes after mixing.

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a Lactona Stimulator, No. 26, Warner-Lambert Pharm. Co. Dist., Morris Plains, New Jersey

b Oral B Stimulator, The Oral B Co., Wayne, New Jersey

c Tee Matrix Bands, P.N. Condit.,Inc., Maynard, Massachusetts

d Jet Carbide Burs, Beavers Dental Products Ltd., Morrisberg, Ontario

e Dedico Midgets, Dental Development & Mfg. Co., Brooklyn, New York

D. Evaluations

1. Baseline and one-year evaluations were conducted by two Public Health examiners from the Materials and Technology Branch, Division of Dental Health.

   a. The base line evaluation was completed within two months after the restorations had been inserted.

   b. The one-year evaluation was carried out after the restorations had been in service for 11 to 13 months.

2. Subsequent annual recall evaluations will also be conducted by the Public Health examiners.

V. <u>Data</u>

A. The collected clinical data was coded for computer analysis by a member of the Materials and Technology Branch, Division of Dental Health, U.S. Public Health Service.

B. Frequency distributions of the various ratings of the restorations was provided.

RESULTS

PART I - LABORATORY STUDY

A. Abrasion Resistance

The comparative data for the abrasion resistance of Adaptic and Velvalloy are listed in Table VI. These data are summarized in Figure 1.

When the specimens were subjected to the abrasive influence of pumice slurries, the resistance to abrasion of Adaptic was approximately four times greater than the resistance of Velvalloy amalgam.

The shadowgraph silhouettes of all the test specimens, which are exhibited in Figures 2 and 3, permit visual perception of the results of these tests.

B. Hardness

The data for the hardness measurements are presented in Table VII. The surface hardness of the Adaptic specimens increased relatively little as they aged from 15 minutes to 24 hours. The average hardness at 15 minutes was 43.6 KHN (Knoop hardness number) and increased to only 49.4 KHN at 24 hours.

There was a significant increase in the average KHN of the Velvalloy specimens as they aged over the same time period. At 15 minutes the amalgam specimens were considerably softer than the Adaptics, having an average KHN of only 9.0. However, their surface hardness approached that of the Adaptic at one hour and increased significantly to an average of 97.4 KHN at 24 hours. Thus the 24 hour hardness of the Velvalloy amalgam was essentially twice that of Adaptic.

C. Marginal Leakage

The results of this study are based on a subjective evaluation of the autoradiographs of each test restoration. Representative autoradiographs of each test group are shown in Figures 4 and 5.

In all groups tested, the marginal seal of the Velvalloy restorations were judged to be slightly superior to the Adaptic restorations.

The Adaptic restorations which were stored in water showed very similar leakage patterns for one week, one month and three month storage periods. The marginal penetration of Ca^{45} allowed by the Adaptic restorations was slight or even undectectable in most instances.

The Velvalloy restorations exhibited quite a similar pattern for the three storage periods. The marginal integrity of these restorations was very good. Essentially no leakage was observed, especially in the three month group of restorations.

The marginal leakage increased proportionately in both groups after the restorations had been subjected to 2500 thermocycles between hot and cold water baths. However, the Velvalloy restorations still exhibited a somewhat superior seal after the cycling (Figure 5).

D. Strength

1. Compressive Strength

All the data for the compressive strength tests on Adaptic and Velvalloy are listed in Tables VIII and IX. These data are summarized in Figures 6 and 7.

Adaptic was found to increase steadily but only slightly in strength with age. It rapidly reaches its maximum strength. The one hour specimens fractured under a compressive load of about 28,000 pounds per square inch while the one month specimens had a strength of only approximately 32,000 pounds per square inch.

The compressive strength of Adaptic was only slightly affected when the Catalyst paste: Universal paste ratio was varied from extremes of 1.0:2.0 to 2.0:1.0 (Table IX).

The compressive strength of the Velvalloy specimens increased markedly with age, not the small increase as with Adaptic. The amalgam material, at one hour, had a strength of approximately 15,000 pounds per square inch but increased to approximately 51,000 pounds per square inch at 24 hours. The one week strengths were essentially comparable to those at 24 hours but at one month further increase to about 55,000 pounds per square inch was observed.

2. Tensile Strength

The data for these tests are found in Table X and illustrated in Figure 8. The tensile strengths of both materials were considerably less than their compressive strengths. However, both materials followed essentially the same general pattern.

The one-hour tensile strength of Adaptic was approximately 4,000 pounds per square inch. In the 24 hour, one week,and one month specimens, tensile strength increased steadily up to a maximum of approximately 6,100 pounds per square inch.

The tensile strength of Velvalloy was only 2,600 pounds per square inch at one hour, but increased sharply to about 8,700 pounds per square inch and remained approximately the same for 24-hour, one week, and one month specimens.

E. Color Stability

As judged by seven different people in two separate tests, Adaptic was found to exhibit a "barely detectable" or "no detectable" color change after exposure to the sunlamp for 24 hours. All examiners agreed that if any visual color change had occurred in any test specimen, it was not readily observable.

F. Staining Characteristics

All data for the staining tests are recorded in Tables XI through XIV. The results of the color tests are summarized in Figures 9 through 14.

The color readings were recorded in National Bureau of Standards (NBS) Color Units as taken from the Hunter Color and Color Difference Meter.

In nearly all instances the finished surfaces of all three materials tested were more susceptible to the three staining media than were the glass slab surfaces. In some instances the color changes were small, even though these staining tests were designed to be much more severe than any staining which might occur in the oral cavity, under normal conditions, during the same period of time.

The methylene blue stain affected the glass slab surface of Addent 12 more than Adaptic or Sevriton. Addent 12 showed color changes of about 17 NBS color difference units on all three color scales. However, the finished surfaces of Adaptic and Sevriton stained with methylene blue were more comparable to the stained, finished surface of Addent 12.

The glass slab surfaces of Addent 12 and Sevriton were influenced considerably by cobalt sulfide on the gray scale; average NBS color difference units of 26.5 and 21.0 respectively were recorded. The glass slab surface of Adaptic was affected only minimally by cobalt sulfide, although the finished surface of Adaptic was the most severely affected by cobalt sulfide (color change in the magnitude of 40 NBS units was measured on the gray scale). Cobalt sulfide did, however, cause significant color changes on the surfaces of all the test specimens that had been finished.

The greatest color changes recorded with lipstick staining were on the red-green scale with an average NBS color difference of approximately 15 units. Changes on the glass slab surfaces of Sevriton specimens were practically negligible and the changes on Adaptic specimens were only slightly greater. The glass slab surfaces of the Addent 12 specimens were considerably greater. The finished surfaces of Adaptic and Addent 12 were equally affected by lipstick and exhibited greater color changes than Sevriton.

The 15-minute brushing periods with toothpaste slurries that some of the stained specimens were given rather effectively removed all the stains from both types of surfaces for all three materials. In four instances the color change after brushing was greater than after the staining procedure. In all four cases, however, color changes were small and within the limits of error of the tests, because the unstained controls had exhibited color changes of the same magnitude.

Only Sevriton showed obvious wear after the 15-minute brushing periods.

Photographs of a portion of the specimens used in the tests and chosen as representative of the results are shown in Figures 15 through 18. It should be pointed out, however, that these black and white prints are somewhat misleading since the actual colors of the specimens are not shown. In the photographs the control Sevriton specimens appear darker than some of the stained specimens. This is because the original shade of the Sevriton specimens was darker than the original Adaptic and Addent 12 specimens. However, since the color difference of each specimen before and after staining is what was actually being recorded, this does not in any way impair the validity of the tests.

G. Solubility

1. Water

The average water solubility data, expressed in milligrams per square centimeter, are listed in Table XV. The five day water solubility for Adaptic was nil. The data recorded for Addent 12 and Sevriton were also quite low and not practically significant.

2. Citric acid

The average solubility data in citric acid are recorded in Table XVI. Addent 12 exhibited no solubility when the cumulative data for the five day period are considered. The five day cumulative data for Adaptic and Sevriton indicate that these materials had a slightly negative solubility; however, these data are within the experimental error of the methodology employed.

H. Water Sorption

The water sorption data of Adaptic collected over a period of 56 days are presented in Table XVII. The specimens continued to sorb water at a very slow rate throughout the testing period. The data indicate that the specimens had not yet reached equilibrium, although they may have been near equilibrium, at the end of the 56 day testing period. A graph summarizing these data is shown in Figure 19. Longer term data are needed to determine when the system truly approaches water equilibrium.

I. Mercury Content

Table XVIII tabulates the mercury content of Velvalloy amalgam specimens which were representative of all types of specimens used in this study, including sample restorations simulating the restorations placed for the clinical investigation. The data show that the average mercury content of all sample specimens was less than 50 per cent.

Part II. INITIAL RESULTS OF THE CLINICAL STUDY

Photographs of representative restorations at the time of the base line examination are shown in Figures 20 and 21. The first annual evaluation was completed and subsequent annual examinations and evaluations of the paired restorations are planned. These one-year data was compared with the initial base line data and statistically analyzed.

Figures 22 through 26 show representative restorations at the first annual evaluation examination. Table XIX summarized clinical results for both the base line and one-year evaluations.

Of the original 124 pairs of restorations placed, 109 pairs were evaluated at the base line examination. Of these 109 pairs which were evaluated at base line, 92 pairs were re-evaluated at one year. Two of these pairs had to be eliminated from the study because the composite restorations had been replaced by clinicians not associated with this study. The reasons for replacement are unknown.

At the base line examination the composite restorations were essentially comparable to the amalgam restorations for anatomic form. However, the data for anatomic form of the paired restorations favored amalgam at the end of one year. Only 70 per cent of the composite restorations received an "Alfa" rating while all the amalgam restorations remained in the "Alfa" category.

The statistical analysis was performed using the data from only one pair of restorations in each patient to maximize the validity of the statistical tests. This left 40 tied pairs (pairs that were rated equal) and 16 untied pairs (one restoration rated superior to the other).

The anatomic form of the amalgam restorations was superior in all 16 untied pairs.

The results of this statistical analysis, using the normal approximation to a binomial, showed that the difference was significant at a probability level of less than .001 ($p < .001$), favoring the amalgam restorations. All of the composite restorations that did change in anatomic form (30 per cent) during the year fell only to the "Bravo" classification and none warranted replacement. In all instances the observed change appeared to be a small loss of material in the marginal ridge area of the restoration.

The one year data for marginal adaptation revealed that 3 per cent of the composite restorations were rated "Bravo" while the remainder retained the "Alfa" rating. However, 13 per cent of the amalgam restorations were rated below "Alfa," 10 per cent were classified as "Bravo," and 3 per cent as "Delta." The amalgams which had "Delta" ratings were fractures and required replacement. There were no fractured composite restorations.

Of the paired restorations included in the statistical analysis for marginal adaptation, there were 43 tied pairs and 13 untied pairs. Ten of the untied pairs favored Adaptic while three favored Velvalloy. A test using the normal approximation to a binomial showed that this difference was in favor of Adaptic and significant at a probability level of less than .03 ($p < .03$).

The base line evaluation revealed no clinical evidence of caries in any of the teeth associated with either material and again at one year no evidence of recurrent caries was detected.

The composite resin restorations were also evaluated for color match and cavo-surface marginal discoloration at the base line and one-year examinations. The base line data show that 83 per cent of the restorations were rated "Alfa" for color match and 72 per cent were rated "Alfa" for cavo-surface margins. At the one-year examination the "Alfas" had fallen to 41 per cent and 48 per cent, respectively, for the same two properties. There was a very high statistical significance favoring the base line for both color match and cavo-surface marginal discoloration. However, none of the restorations were rated below "Bravo" for either color match or marginal stain, so all restorations remained within the normal range for tooth color and/or translucency. Interestingly, although 83 per cent of the Adaptic restorations were rated "Alfa" for color match at the base line examination, there had been no conscious effort by the operators to actually match the tooth shade when the restorations were placed. One shade of resin was used throughout the study.

TABLES AND FIGURES

TABLE I

Clinical Criteria for Anatomic Form

Code Word	Code	Clinical Criterion
Alfa	A	The restoration is continuous with existing anatomic form.
Bravo	B	The restoration is discontinuous with existing anatomic form but the missing material is not sufficient to expose dentin or base.
Charlie	C	Sufficient material lost to expose dentin or base.

TABLE II

Clinical Criteria for Marginal Adaptation

Code Word	Code	Clinical Criterion
Alfa	A	The restoration appears to adapt closely to the tooth along the periphery of the restoration. An explorer does not catch when drawn across the margins, or, if it does catch it is only in one direction and no crevice is visible.
Bravo	B	The explorer catches and there is visible evidence of a crevice into which the explorer will penetrate. However, dentin or base is not visible.
Charlie	C	The explorer penetrates into a crevice that is of such depth that dentin or base is exposed.
Delta	D	The restoration is fractured mobile or missing.

TABLE III

Clinical Criteria for Caries

Code Word	Code	Clinical Criterion
Alfa	A	There is no evidence of caries[a] contiguous with the margin of the restoration.
Bravo	B	There is evidence of caries[a] contiguous with the margin of the restoration.

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a An area at the restoration margin is carious if an explorer "catches" or resists removal after insertion with moderate to firm pressure, and is accompanied by one or more of the following:

a. softness,
b. opacity at the margin, as evidence of undermining or demineralization,
c. etching or a white spot as evidence of demineralization.

An area at the margin is also considered carious if the explorer does not "catch", but conditions b or c are present.

TABLE IV

Clinical Criteria for Color Match

Code Word	Code	Clinical Criterion
Alfa	A	There is a match in color, shade and/or translucency between the restoration and the adjacent tooth structure.
Bravo	B	The mismatch between the restoration and adjacent tooth structure is not outside the normal range of tooth color, shade and/or translucency.
Charlie	C	The mismatch is outside the normal range of tooth color, shade and/or translucency.
Hotel	H	The restorative material is metallic.

TABLE V

Clinical Criteria for Cavo-Surface Marginal Discoloration

Code Word	Code	Clinical Criterion
Alfa	A	There is no discoloration anywhere on the margin between the restoration and the tooth structure.
Bravo	B	There is discoloration somewhere on the margin of the restoration, but it has not penetrated inwardly.
Charlie	C	The discoloration has penetrated along the margin of the restorative material in a pulpal direction.
Hotel	H	The restoration is metallic.

TABLE VI

Abrasion Resistance to Flour of Pumice Slurry

24-Hour Specimens Brushed One Hour (9000 Strokes)

Material	Spec. No.	Original Wt.(mg)	Final Wt.(mg)	Weight Loss (mg)	% Wt. Loss
Adaptic	1	621.8	616.4	5.4	0.87
	2	654.4	648.6	5.8	0.89
	3	657.4	652.2	5.2	0.79
	4	617.7	611.4	6.3	1.02
				Average	0.89
				S.D.	0.09
Velvalloy	1	3465.4	3334.0	131.4	3.79
	2	3459.1	3316.6	142.5	4.12
	3	3463.6	3353.6	110.0	3.18
	4	3463.1	3310.2	152.9	4.42
				Average	3.88
				S.D.	0.53

TABLE VII

Surface Hardness
(Knoop Hardness Numbers)

Material	Spec. No.	15 Minutes	One Hour	24 Hours
Adaptic	1	42.5	42.1	48.2
	2	-	45.8	50.2
	3	44.7	44.6	49.7
	Ave.	43.6	44.2	49.4
Velvalloy	1	6.4	33.4	88.2
	2	7.9	45.1	91.4
	3	10.4	-	94.2
	4	11.5	31.6	105.0
	5	8.6	29.4	108.0
	Ave.	9.0	34.9	97.4

TABLE VIII

Compressive Strength

Spec. No.	One Hour (psi) Adaptic	One Hour (psi) Velvalloy	24 Hours (psi) Adaptic	24 Hours (psi) Velvalloy
1	25,800	15,800	28,300	53,300
2	29,100	14,000	27,800	53,000
3	30,000	15,000	27,600	53,300
4	29,400	15,700	28,400	52,000
5	26,450	14,000	29,300	51,000
6	26,100	12,000	26,100	47,000
7	28,400	15,700	27,400	50,500
8	29,200	15,700	28,200	54,500
9	28,600	17,500	29,700	43,600
10	28,300	13,500	28,200	
11	29,200	14,500	33,000	
12		13,600	29,100	
13		16,600	25,100	
14		16,000	31,900	
15		14,700	29,300	
16		17,700	30,800	
17		16,300		
18		18,000		
19		15,300		
20		17,000		
Ave.	28,200	15,400	28,800	50,900
S.D.	1,400	1,500	1,900	3,300

TABLE VIII (continued)

Spec. No.	One Week (psi) Adaptic	One Week (psi) Velvalloy	One Month (psi) Adaptic	One Month (psi) Velvalloy
1	27,900	54,100	36,000	57,800
2	30,500	49,500	35,600	52,100
3	27,600	43,400	35,000	58,100
4	26,100	52,600	34,700	55,300
5	23,200	55,800	36,000	50,800
6	26,600	52,600	37,100	49,200
7	30,000	51,000	35,900	54,900
8	30,900	44,400	25,400	56,600
9	30,400	53,000	32,400	58,700
10	33,000	52,500	33,400	56,800
11	30,400	47,000	30,400	
12	31,700	54,900	31,300	
13	29,800	48,200	30,500	
14	31,500	61,900	28,400	
15	29,600	45,400	32,300	
16	30,400		32,800	
17	33,600		26,100	
18	32,400		26,800	
19	32,900		30,200	
20	32,700		28,800	
21	30,900		32,700	
22	32,500		29,300	
Ave.	30,200	51,100	31,900	55,000
S.D.	2,500	4,400	3,400	3,100

TABLE IX

Compressive Strength of Adaptic

Different $\frac{\text{Catalyst Paste}}{\text{Universal Paste}}$ Ratios

One Week (psi)

Spec. No.	1.0/2.0 Ratio	1.0/1.0 Ratio	2.0/1.0 Ratio
1	30,900	33,600	35,300
2	32,000	32,400	33,500
3	32,200	32,900	34,500
4	31,200	32,700	33,900
5	31,900	30,900	34,800
6		32,500	
Ave.	31,600	32,500	34,400
S.D.	560	870	710

TABLE X

Tensile Strength

Spec. No.	One Hour (psi) Adaptic	One Hour (psi) Velvalloy	24 Hours (psi) Adaptic	24 Hours (psi) Velvalloy
1	4,100	2,500	3,800	9,600
2	3,700	2,300	4,000	8,300
3	4,100	2,500	4,400	8,400
4	4,300	2,500	4,600	9,800
5	3,900	3,200	3,900	9,100
6	3,000	2,600	5,000	8,200
7	3,800	2,800	4,700	8,400
8	3,700	2,500	4,600	8,800
9	3,800	2,500	4,700	8,200
10	4,300	2,800	5,300	8,400
11	4,600			8,700
12	3,600			
13	4,500			
14	4,700			
15	4,400			
Ave.	4,000	2,600	4,500	8,700
S.D.	450	240	460	530

TABLE X (continued)

Spec. No.	One Week (psi) Adaptic	One Week (psi) Velvalloy	One Month (psi) Adaptic	One Month (psi) Velvalloy
1	5,100	8,800	4,700	9,300
2	4,900	7,600	6,600	7,800
3	5,600	8,900	5,400	8,200
4	6,600	8,200	6,400	8,600
5	4,900	9,100	6,400	7,500
6	4,800	8,700	5,300	8,400
7	5,000	8,400	7,100	9,800
8	5,200	8,300	7,200	9,200
9	4,800	8,400	6,100	
10	4,900	9,200	5,800	
11	6,000	9,400		
12	6,100	8,200		
13	5,700	8,800		
14	6,400	11,100		
15	5,200	8,600		
16	6,000	12,500		
17		7,500		
18		7,700		
19		7,300		
Ave.	5,500	8,800	6,100	8,600
S.D.	590	1,220	760	740

TABLE XI

Staining with Methylene Blue

Glass Slab Surface

Material	Spec. No.	Original Rd	Original a	Original b	Stained Rd	Stained a	Stained b	Brushed Rd	Brushed a	Brushed b
Adaptic	1	61.6	+1.7	+8.1	55.0	-7.9	+3.2	63.4	+1.6	+6.7
	2	60.6	+1.7	+8.2	52.7	-8.2	+2.9	63.1	+1.7	+6.9
	3	60.4	+1.6	+7.8	52.8	-9.0	+2.5			
	4	61.4	+1.8	+8.4	51.6	-9.9	+0.9			
	5	59.4	+1.7	+8.4	52.2	-8.8	+2.6			
Addent 12	31	58.3	+0.8	+9.3	34.1	-18.0	-12.5	59.3	-4.0	+4.1
	32	59.8	+1.6	+4.2	39.7	-16.4	-14.9	62.8	+0.9	+2.5
	33	55.4	+2.0	+5.2	44.9	-11.1	-6.1			
	34	58.4	+1.6	+3.8	43.3	-14.0	-10.6			
	35	62.4	+1.8	+4.6	44.5	-17.5	-12.6			
Sevriton	61	51.6	+1.0	+13.0	43.5	-5.8	+5.2	49.7	+0.1	+8.2
	62	50.0	+1.1	+13.7	44.3	-4.7	+7.4	48.0	-1.1	+8.1
	63	50.9	+0.9	+13.3	45.7	-2.4	+8.8			
	64	51.8	+1.1	+12.6	45.3	-4.8	+5.7			
	65	51.6	+1.1	+13.5	44.7	-5.7	+6.5			

TABLE XI (continued)

Finished Surface

Material	Spec. No.	Original			Stained			Brushed		
		Rd	a	b	Rd	a	b	Rd	a	b
Adaptic	16	69.7	+2.3	+10.2	54.4	-7.3	-2.9	68.3	+2.5	+8.0
	17	64.9	+2.1	+9.1	50.1	-6.9	-3.0	62.6	+2.0	+7.1
	18	65.2	+2.4	+9.6	52.3	-6.9	-1.6			
	19	63.1	+2.2	+9.0	48.0	-7.5	-3.7			
	20	64.3	+2.2	+8.7	50.6	-6.5	-2.6			
Addent 12	46	61.5	+0.5	+9.1	44.4	-12.2	-5.7	59.6	-1.0	+7.2
	47	64.9	+1.5	+3.7	44.7	-12.5	-12.4	63.7	+0.9	+3.0
	48	59.4	+2.0	+4.5	39.9	-10.2	-11.4			
	49	63.7	+1.5	+3.7		lost				
	50	62.9	+1.6	+3.7	48.3	-9.4	-9.2			
Sevriton	76	53.2	+0.8	+12.0	39.7	-6.9	+1.5	50.1	-0.9	+9.3
	77	54.5	+1.2	+12.0	43.1	-5.4	+2.4	48.8	+0.2	+8.7
	78	56.4	+1.1	+11.4	44.8	-6.1	+1.3			
	79	56.3	+1.2	+11.7	44.9	-5.0	+2.1			
	80	54.3	+1.4	+12.8	41.1	-7.9	+0.9			

TABLE XII

Staining with Cobalt Sulfide

Glass Slab Surface

Material	Spec. No.	Original Rd	Original a	Original b	Stained Rd	Stained a	Stained b	Brushed Rd	Brushed a	Brushed b
Adaptic	6	60.6	+1.8	+9.2	56.6	+2.1	+8.9	62.9	+2.1	+7.0
	7	60.8	+2.0	+10.5	58.2	+2.2	+9.1	63.7	+2.5	+7.2
	8	61.2	+1.8	+9.7	50.3	+1.7	+7.3			
	9	61.5	+2.0	+10.6	55.6	+2.2	+8.5			
	10	60.3	+2.2	+10.4	55.2	+2.4	+8.5			
Addent 12	36	56.9	+1.0	+9.3	50.8	+1.5	+8.2	59.3	+1.0	+7.4
	37	59.4	+1.7	+3.8	21.5	+0.3	+2.1	62.3	+1.7	+2.6
	38	57.5	+0.9	+9.2	25.8	+0.4	+2.4			
	39	55.9	+2.2	+4.8	29.3	+0.6	+2.2			
	40	59.1	+1.6	+3.6	29.1	+1.2	+3.0			
Sevriton	66	51.2	+1.1	+13.4	35.6	+1.7	+8.3	49.8	+1.4	+9.8
	67	50.8	+1.1	+13.5	27.6	+1.7	+6.8	47.6	+1.1	+8.9
	68	50.4	+1.1	+13.0	31.5	+2.0	+8.3			
	69	49.8	+0.8	+12.9	29.6	+2.0	+8.2			
	70	51.3	+1.0	+12.8	24.1	+1.5	+6.5			

TABLE XII (continued)

Finished Surface

Material	Spec. No.	Original Rd	Original a	Original b	Stained Rd	Stained a	Stained b	Brushed Rd	Brushed a	Brushed b
Adaptic	21	64.2	+2.2	+8.7	22.4	+0.2	+2.7	58.0	+2.2	+6.8
	22	64.8	+2.2	+8.3	25.0	+0.3	+2.8	61.9	+2.3	+6.9
	23	65.0	+2.3	+9.0	23.6	+0.7	+2.9			
	24	65.6	+2.3	+8.8	27.0	+0.6	+2.4			
	25	64.0	+2.3	+8.9	23.9	+0.8	+3.5			
Addent 12	51	63.0	+0.9	+8.1	28.8	0.0	+2.8	59.6	+0.8	+6.6
	52	66.0	+1.7	+4.5	28.4	+0.3	+2.6	62.9	+1.9	+3.7
	53	62.1	+1.0	+9.5	25.3	+0.2	+2.0			
	54	63.2	+1.6	+4.0	27.5	+0.4	+2.2			
	55	63.2	+1.7	+3.9	23.7	+0.5	+2.3			
Sevriton	81	55.7	+0.8	+11.5	23.2	+0.7	+2.7	48.6	+1.5	+9.0
	82	54.6	+1.1	+12.4	19.6	+0.4	+2.5	50.4	+1.5	+10.4
	83	55.0	+1.5	+12.6	20.6	+0.3	+1.3			
	84	54.6	+1.5	+12.7	24.3	+0.5	+2.4			
	85	54.0	+1.7	+12.8	19.9	+0.4	+2.3			

TABLE XIII

Staining with Lipstick

Glass Slab Surface

Material	Spec. No.	Original Rd	Original a	Original b	Stained Rd	Stained a	Stained b	Brushed Rd	Brushed a	Brushed b
Adaptic	11	61.3	+1.8	+10.1	58.6	+5.2	+8.4	63.4	+2.7	+7.3
	12	59.6	+1.8	+9.6	56.5	+5.9	+8.0	62.2	+2.7	+7.0
	13	59.9	+1.9	+10.3	57.3	+5.7	+8.8			
	14	60.1	+2.0	+10.2	57.6	+5.7	+8.6			
	15	60.5	+2.2	+10.9	57.2	+6.9	+8.9			
Addent 12	41	58.5	+1.0	+9.6	53.9	+10.9	+7.1	62.1	+1.4	+7.2
	42	57.8	+2.3	+5.0	47.5	+21.8	+2.7	60.5	+3.7	+3.5
	43	59.9	+2.0	+4.1	52.0	+18.0	+2.0			
	44	59.1	+1.8	+3.7	51.1	+16.8	+1.5			
	45	60.7	+1.9	+4.2	52.3	+16.9	+2.7			
Sevriton	71	52.8	+0.7	+11.0	52.3	+2.2	+10.0	53.3	+2.0	+9.5
	72	50.5	+0.7	+12.9	50.5	+2.6	+11.7	52.0	+1.9	+10.5
	73	52.4	+1.6	+14.5	52.6	+2.9	+13.3			
	74	52.3	+1.2	+12.8	49.6	+6.7	+10.8			
	75	51.4	+1.2	+13.3	50.4	+3.3	+11.8			

TABLE XIII (continued)

Finished Surface

Material	Spec. No.	Original Rd	Original a	Original b	Stained Rd	Stained a	Stained b	Brushed Rd	Brushed a	Brushed b
Adaptic	26	65.5	+2.2	+8.4	53.7	+16.1	+6.9	63.3	+3.2	+7.9
	27	64.3	+2.2	+8.4	51.1	+18.5	+6.3	61.3	+4.6	+7.6
	28	63.6	+2.3	+8.8	53.1	+14.8	+6.9			
	29	65.5	+2.2	+8.5	52.0	+18.7	+6.6			
	30	65.4	+2.3	+8.8	54.4	+15.9	+7.1			
Addent 12	56	62.3	+1.0	+9.3	48.8	+19.9	+6.3	61.8	+2.6	+7.4
	57	60.5	+2.0	+4.1	51.0	+14.2	+3.2	59.1	+3.0	+3.8
	58	64.2	+1.7	+4.0	54.7	+14.1	+2.9			
	59	61.3	+2.2	+4.5	52.1	+14.2	+3.2			
	60	66.5	+2.2	+5.0	55.5	+17.5	+3.5			
Sevriton	86	53.8	+1.4	+12.1	44.6	+11.7	+9.9	50.6	+1.9	+10.9
	87	54.8	+1.1	+11.5	46.2	+11.7	+9.4	51.6	+2.9	+10.9
	88	56.8	+1.1	+11.5	50.5	+10.0	+9.6			
	89	53.3	+1.3	+12.3	45.6	+11.3	+10.3			
	90	53.7	+1.3	+12.0	46.6	+8.9	+10.4			

TABLE XIV

Unstained Controls

Glass Slab Surface

Material	Spec. No.	Original Rd	Original a	Original b	Stored in Water Rd	Stored in Water a	Stored in Water b	Brushed Rd	Brushed a	Brushed b
Adaptic	1	61.6	+1.9	+9.8	61.6	+2.1	+7.9			
	2	60.1	+2.0	+9.9	60.1	+2.1	+8.2	63.2	+2.1	+7.5
Addent 12	3	59.7	+1.7	+3.7	59.9	+1.7	+3.2			
	4	59.5	+1.7	+3.3	59.7	+1.7	+3.0	63.5	+1.7	+2.5
Sevriton	5	51.9	+1.6	+13.0	52.0	+1.3	+11.0			
	6	51.3	+2.5	+13.7	51.4	+2.2	+12.0	51.7	+2.4	+11.9

Finished Surface

Material	Spec. No.	Original Rd	Original a	Original b	Stored in Water Rd	Stored in Water a	Stored in Water b	Brushed Rd	Brushed a	Brushed b
Adaptic	7	64.9	+2.4	+9.3	63.8	+2.4	+8.6			
	8	66.0	+2.3	+8.9	64.8	+2.5	+8.3	65.4	+2.7	+8.3
Addent 12	9	64.4	+2.0	+3.1	63.3	+2.0	+3.3			
	10	64.0	+2.0	+3.1	63.0	+2.0	+3.4	63.5	+2.1	+3.2
Sevriton	11	55.2	+2.0	+11.7	53.4	+1.9	+11.3			
	12	55.8	+2.5	+12.0	54.7	+2.4	+11.4	51.5	+2.9	+12.8

TABLE XV

Average Water Solubility[a]

(mg/cm^2)

Material	Day 1	Day 2	Day 3	Day 4	Day 5	5-Day Total
Adaptic	0	0	+0.09	-0.09	0	0
Addent 12	+0.09	0	+0.09	+0.17	+0.04	+0.39
Sevriton	+0.17	0	+0.09	+0.13	-0.04	+0.35

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a All values represent the average weight increase/surface area of four specimens.

TABLE XVI

Average Citric Acid Solubility[a]

(mg/cm^2)

Material	Day 1	Day 2	Day 3	Day 4	Day 5	5-Day Total
Adaptic	0	+0.04	-0.35	-0.04	+0.13	-0.22
Addent 12	0	+0.22	-0.22	-0.13	+0.13	0
Sevriton	+0.09	-0.04	-0.22	-0.17	+0.17	-0.17

---

a All values represent the average weight increase/surface area of four specimens.

TABLE XVII

Water Sorption of Adaptic

(mg/cm^2)

Spec. No.	1 Day	2 Days	3 Days	4 Days	7 Days	9 Days
1	0.33	0.20	0.26	0.39	0.41	0.41
2	0.19	0.09	0.18	0.25	0.24	0.27
3	0.18	0.15	0.19	0.25	0.29	0.28
4	0.18	0.12	0.19	0.26	0.25	0.27
5	0.08	0.05	0.06	0.18	0.14	0.17
Ave.	0.19	0.12	0.18	0.27	0.27	0.28
S.D.	0.09	0.06	0.07	0.08	0.10	0.08

	14 Days	28 Days	35 Days	42 Days	49 Days	56 Days
1	0.59	0.79	0.85	0.85	0.89	0.95
2	0.37	0.60	0.65	0.66	0.72	0.74
3	0.39	0.57	0.60	0.64	0.72	0.74
4	0.35	0.55	0.59	0.62	0.72	0.72
5	0.27	0.49	0.53	0.53	0.59	0.64
Ave.	0.39	0.60	0.64	0.66	0.73	0.76
S.D.	0.12	0.11	0.12	0.12	0.11	0.11

TABLE XVIII

Mercury Content of Various Velvalloy Specimens

(Per cent mercury by weight)

Spec. No.	Abrasion	Hardness	Marginal Leakage
1	45.5	50.0	48.4
2	45.8	49.0	46.9
3	45.0	48.9	47.5
4	45.5	49.4	47.8
5	44.4	49.6	47.4
6		50.6	46.4
Ave.	45.2	49.6	47.4
S.D.	0.5	0.6	0.6

	Strength	Clinical Facsimiles
1	45.8	50.1
2	46.2	46.5
3	46.4	47.4
4	46.4	48.1
5	47.6	49.2
6	45.3	49.3
Ave.	46.3	48.4
S.D.	0.7	1.2

TABLE XIX

Base Line and One-Year Clinical Results

			Restorations Examined	Alfa	Bravo	Charlie	Delta	Replaced
Anatomic Form	Base Line	Composite	109	108	1			
		Amalgam	109	109				
	One Year	Composite	92	71	19			2[a]
		Amalgam	92	92				
Marginal Adaptation	Base Line	Composite	109	104	5			
		Amalgam	109	108	1			
	One Year	Composite	92	87	3			2[a]
		Amalgam	92	80	9		3	
Color Match	Base Line	Composite	109	90	19			
	One Year	Composite	92	37	53			2[a]
Cavo-Surface Marginal Discolor-ation	Base Line	Composite	109	79	30			
	One Year	Composite	92	43	47			2[a]

a Restorations replaced at another facility - reason unknown.

Figure 1: Comparison of abrasion resistance of Adaptic and Velvalloy.

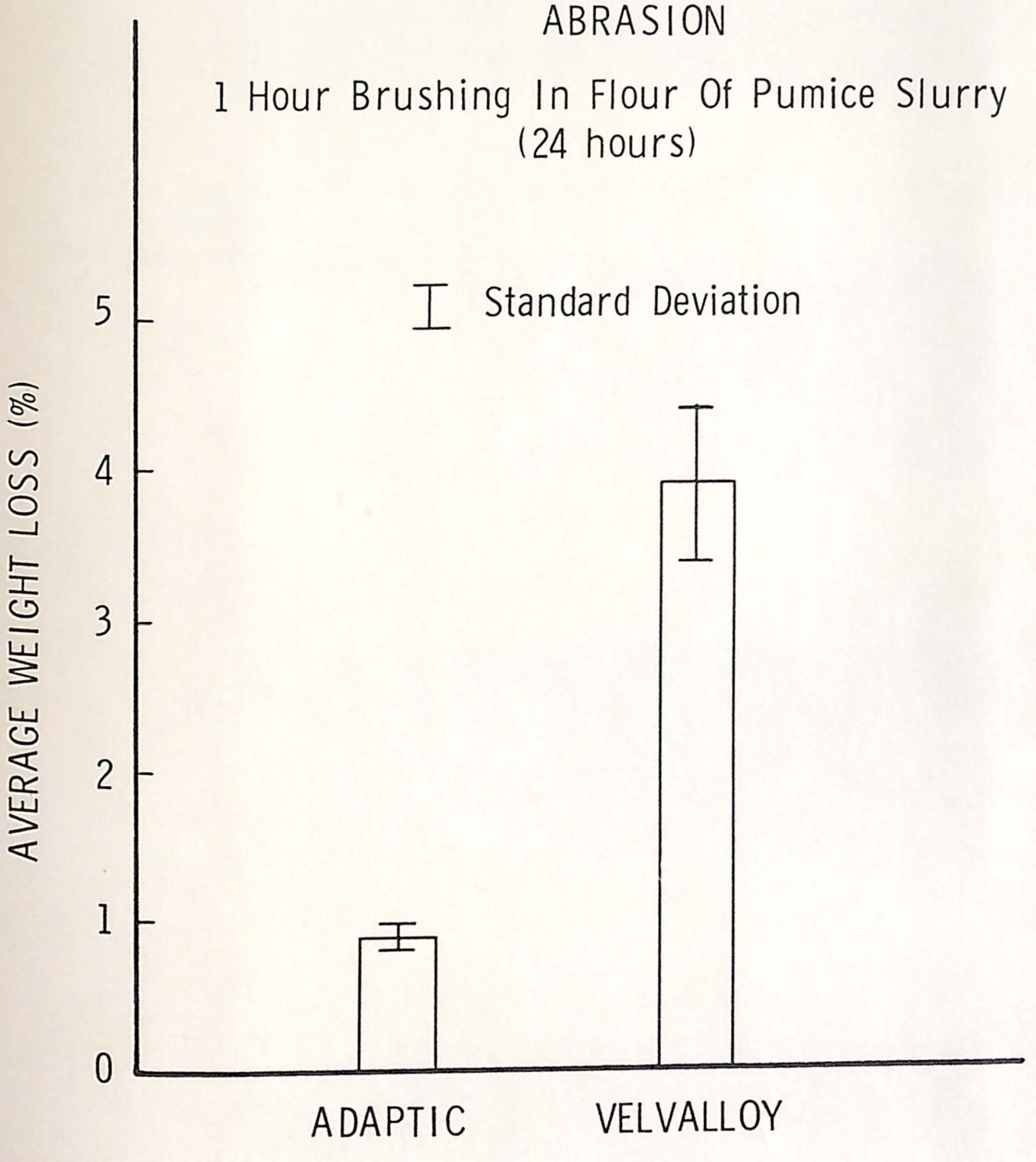
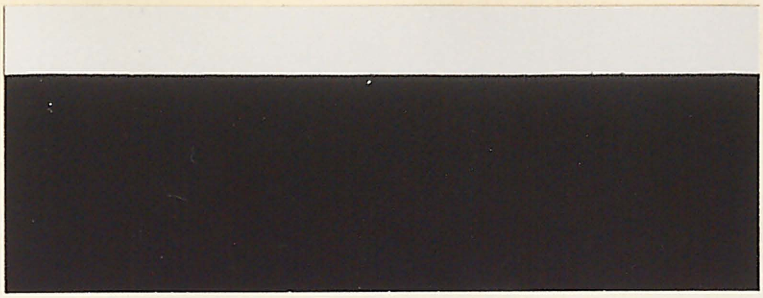
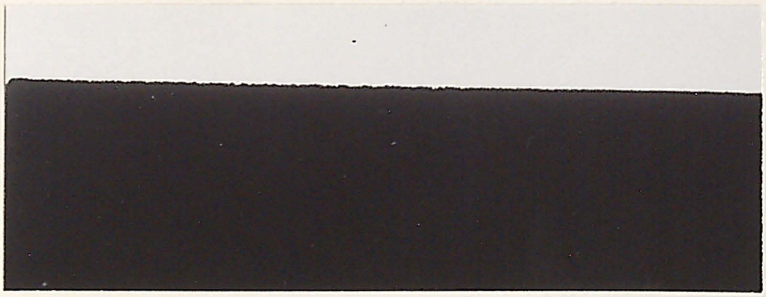

ABRASION
1 Hour Brushing In Flour Of Pumice Slurry
(24 hours)
Standard Deviation
AVERAGE WEIGHT LOSS (%)
0
1
2
3
4
5
ADAPTIC
VELVALLOY

Figure 2: Silhouettes of Adaptic specimens before and after brushing. Specimen A was the unbrushed control and Specimens B through E were brushed for one hour in a slurry of flour of pumice.

A

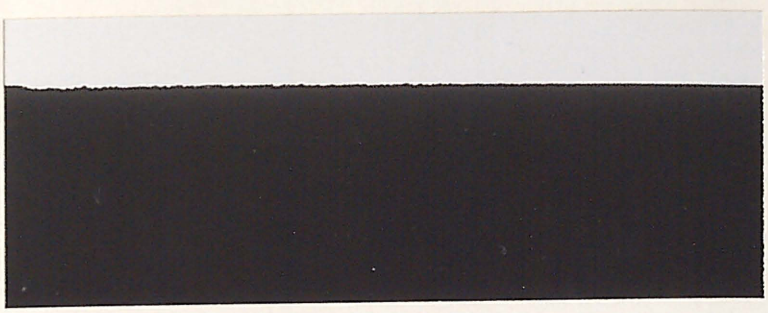


B



C

D



E

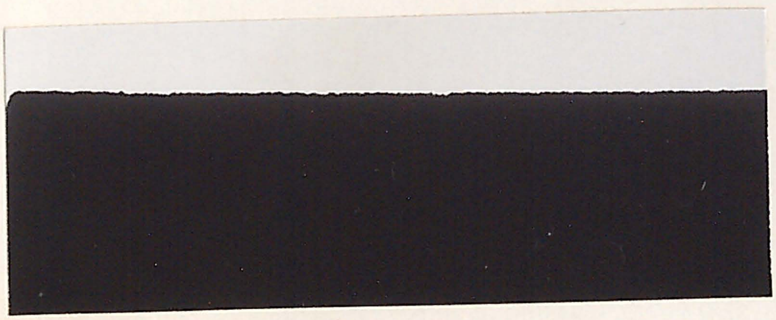
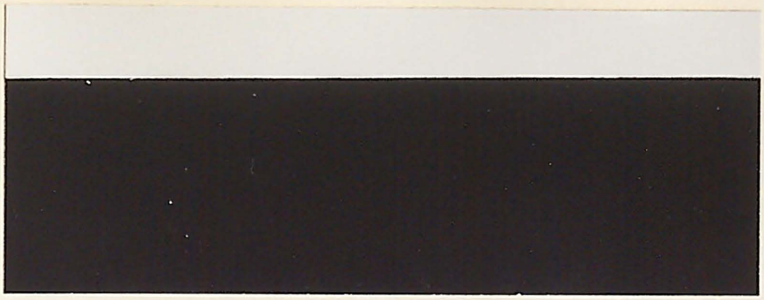


Figure 3: Silhouettes of Velvalloy specimens before and after brushing. Specimen A was the unbrushed control and Specimens B through E were brushed for one hour in a slurry of flour of pumice.

A



B

C

D

E

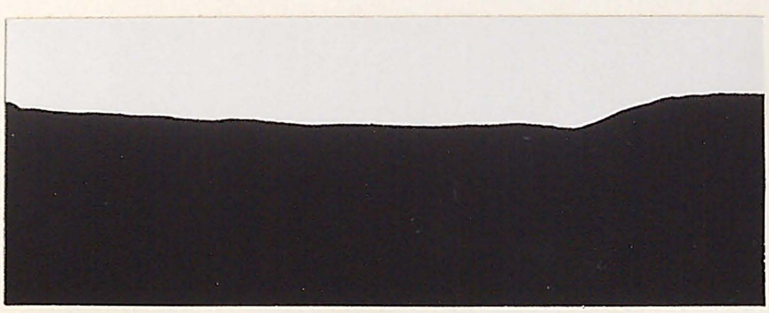
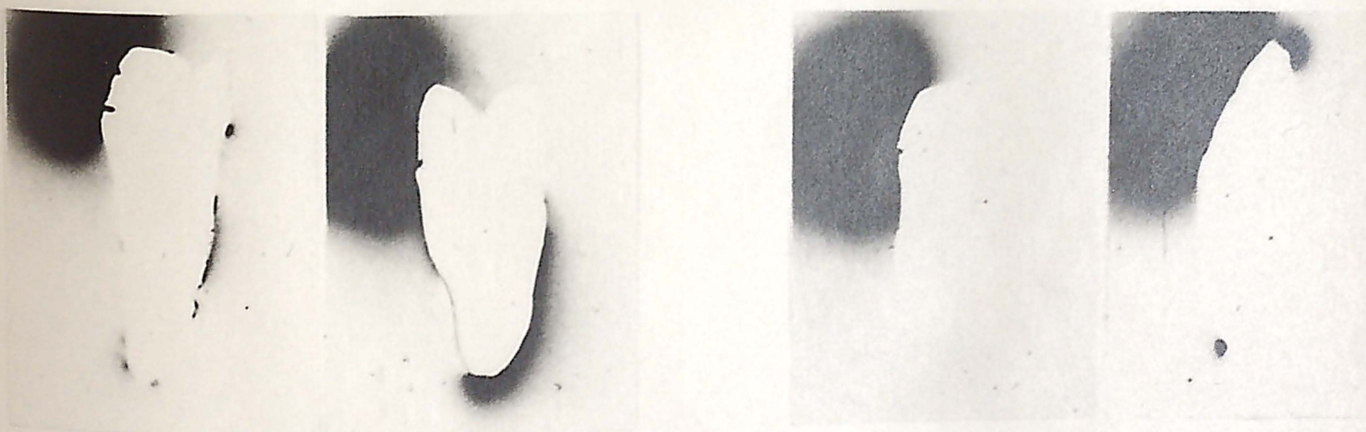


Figure 4: Autoradiographs of stored restorations representative of the marginal leakage patterns at various time intervals. (The black line at the margin of the restorations indicates the penetration by the isotope.)

STORAGE IN WATER

ADAPTIC VELVALLOY

One Week



One Month

Three Months

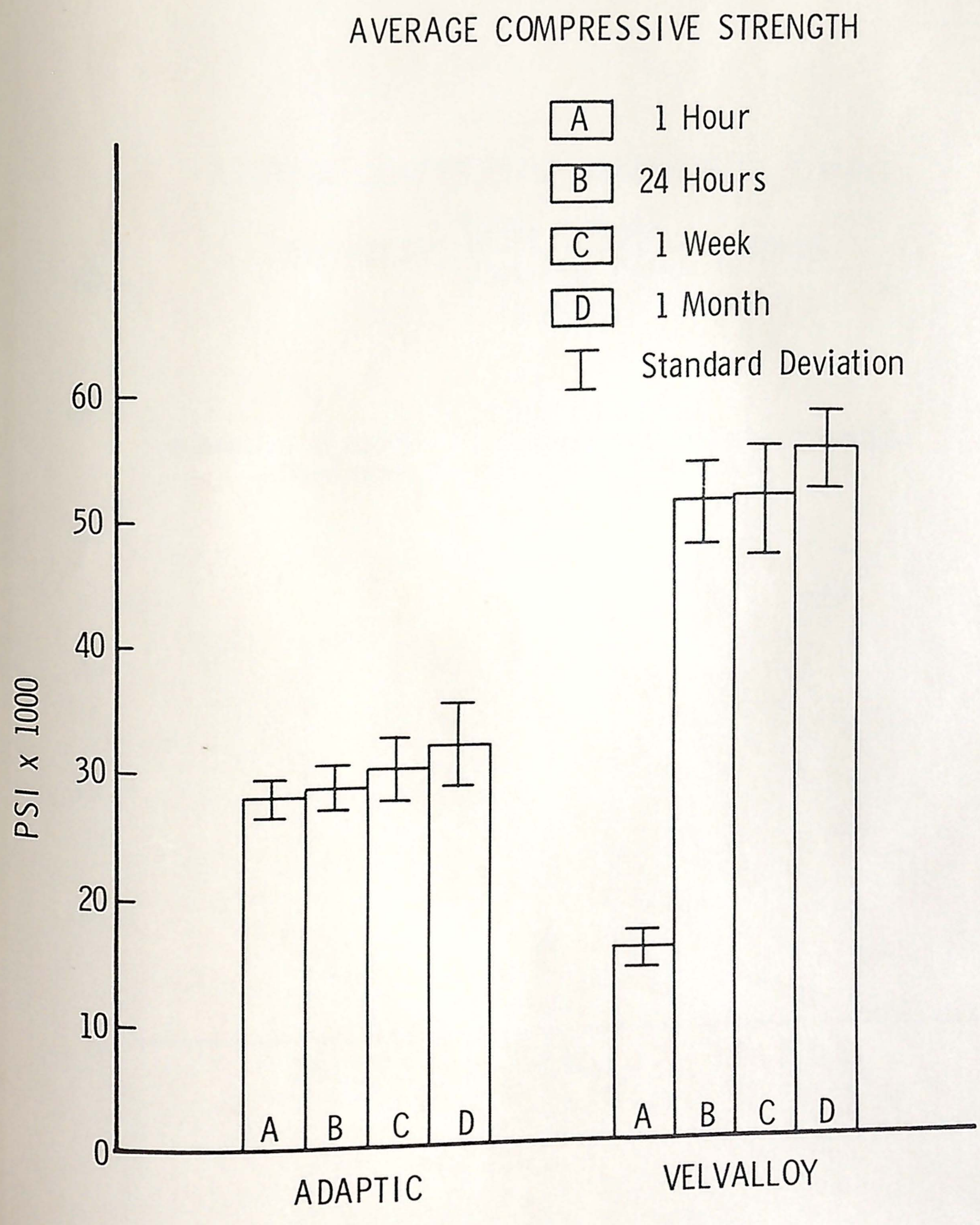
Figure 5: Representative autoradiographs illustrating the leakage patterns of restorations subjected to thermocycling.

THERMOCYCLED IN WATER
(2500 cycles, 40^{o}C Gradient)

ADAPTIC VELVALLOY

One Week

Figure 6: Comparison of the compressive strengths of Adaptic and Velvalloy.



AVERAGE COMPRESSIVE STRENGTH
A 1 Hour
B 24 Hours
C 1 Week
D 1 Month
Standard Deviation
PSI x 1000
0
10
20
30
40
50
60
A
B
C
D
A
B
C
D
ADAPTIC
VELVALLOY

Figure 7: Compressive strength of Adaptic as related to Catalyst Paste: Universal Paste ratio.

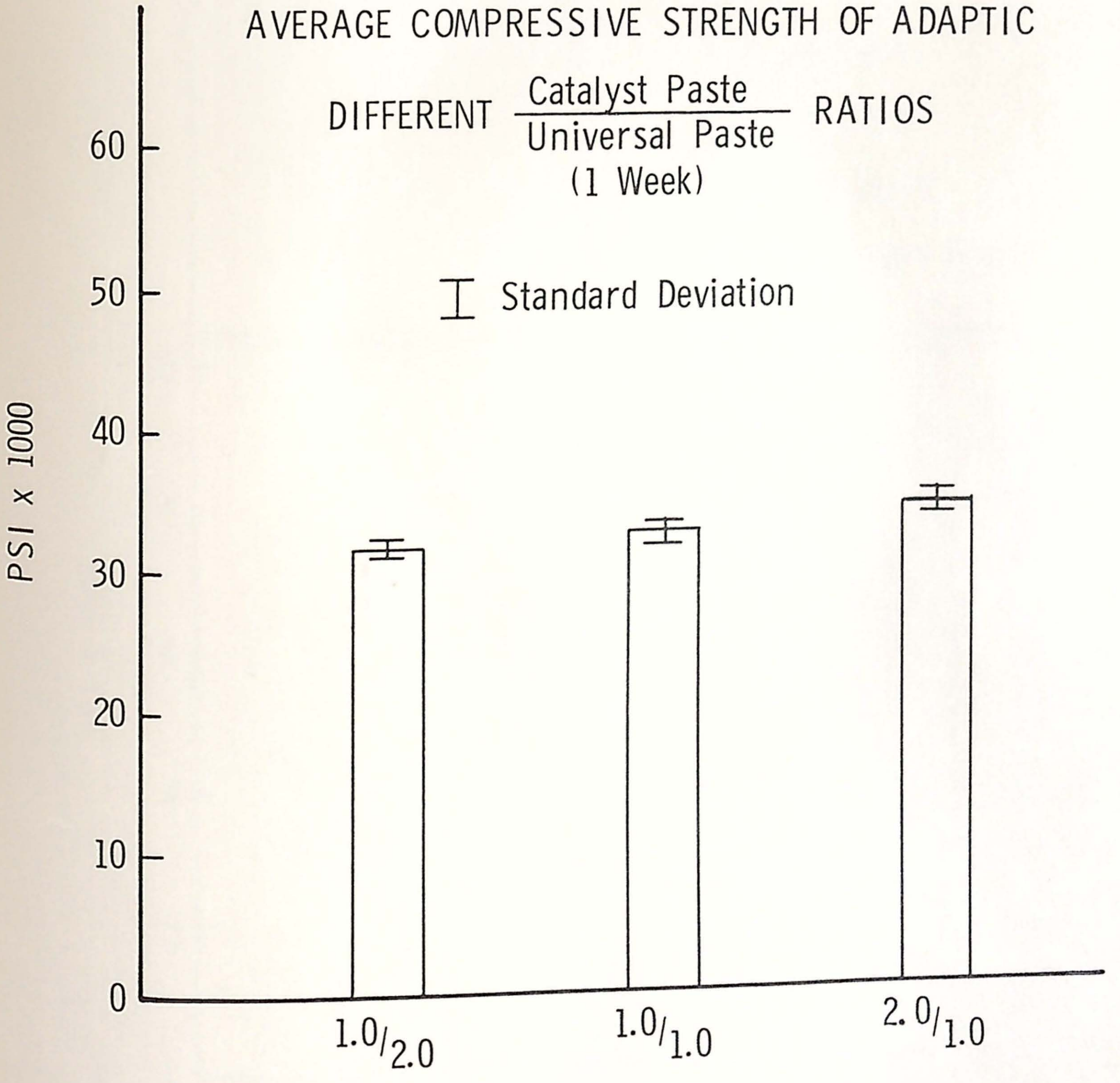

AVERAGE COMPRESSIVE STRENGTH OF ADAPTIC
DIFFERENT Catalyst Paste / Universal Paste RATIOS
(1 Week)
Standard Deviation
PSI x 1000
60
50
40
30
20
10
0
1.0/2.0
1.0/1.0
2.0/1.0

Figure 8: Comparison of the tensile strengths of Adaptic and Velvalloy.

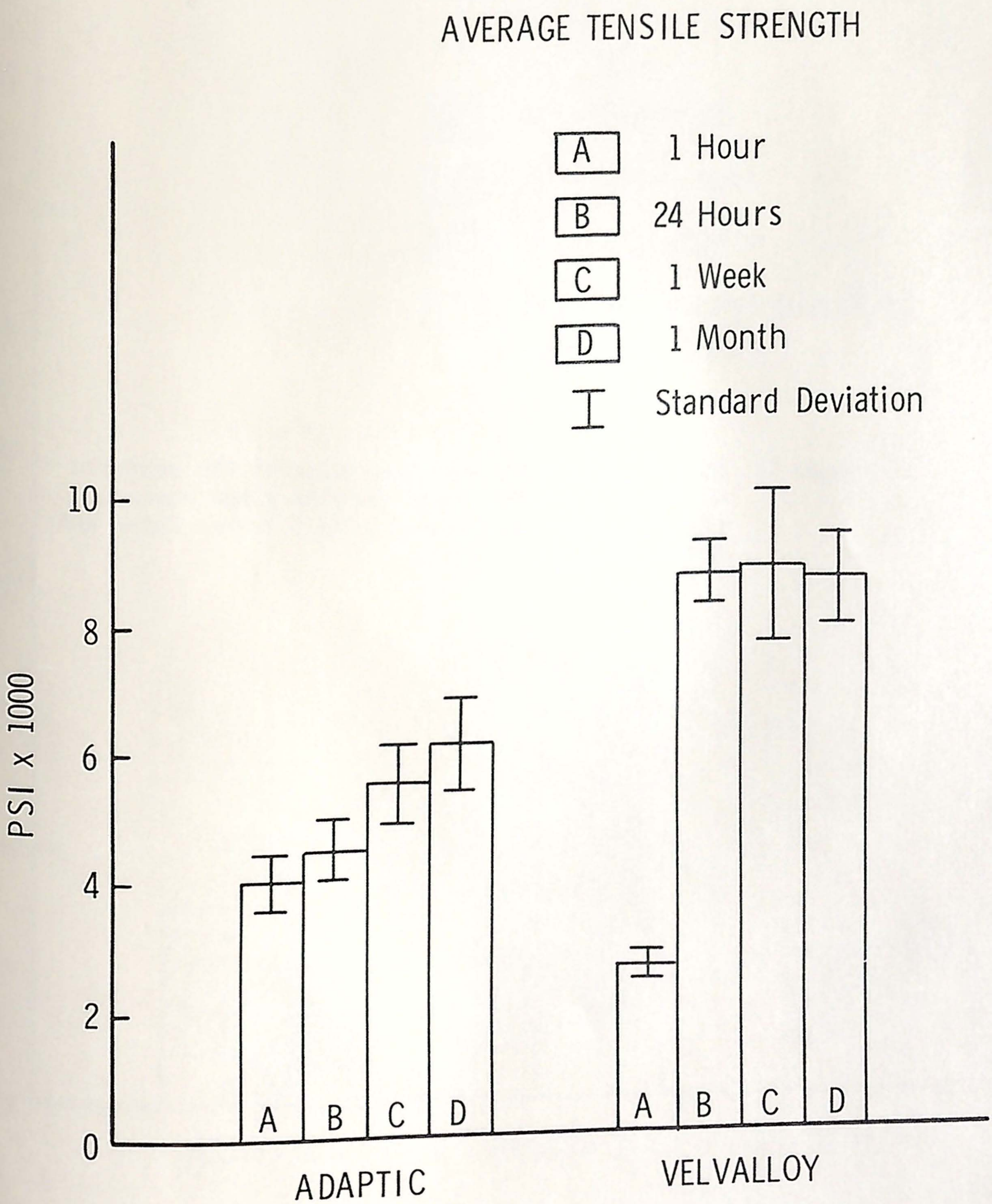

AVERAGE TENSILE STRENGTH
A 1 Hour
B 24 Hours
C 1 Week
D 1 Month
Standard Deviation
PSI x 1000
0
2
4
6
8
10
A
B
C
D
A
B
C
D
ADAPTIC
VELVALLOY

Figure 9: Stain produced by methylene blue on the surfaces of resin specimens cured between glass plates. Color change was measured with a Hunter Color and Color Difference Meter.

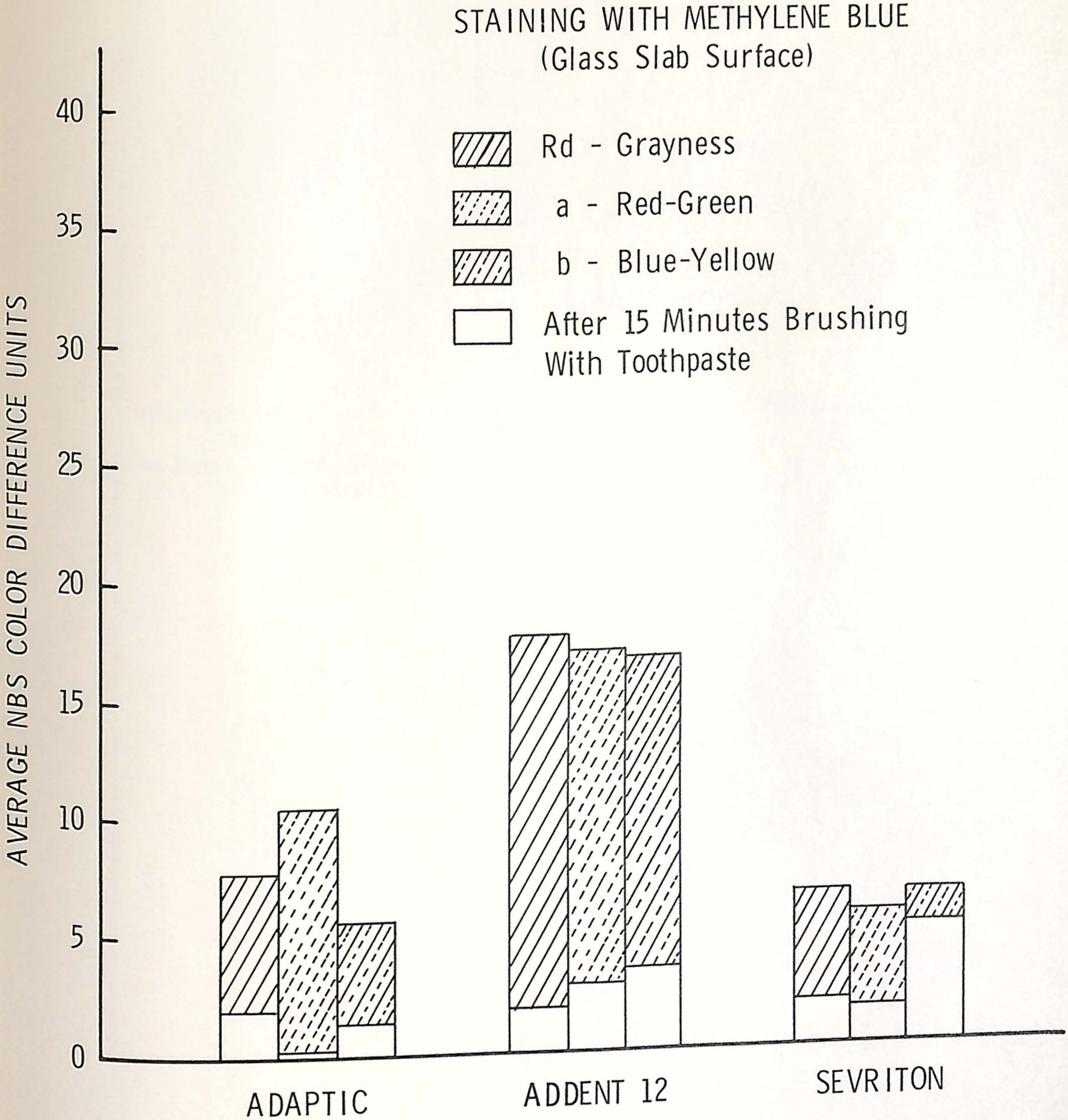

STAINING WITH METHYLENE BLUE
(Glass Slab Surface)
Rd - Grayness
a - Red-Green
b - Blue-Yellow
After 15 Minutes Brushing With Toothpaste
AVERAGE NBS COLOR DIFFERENCE UNITS
40
35
30
25
20
15
10
5
0
ADAPTIC
ADDENT 12
SEVRITON

Figure 10: Stain produced by methylene blue on the surfaces of resin specimens finished with 400A grit carborundum paper. Color change was measured with a Hunter Color and Color Difference Meter.

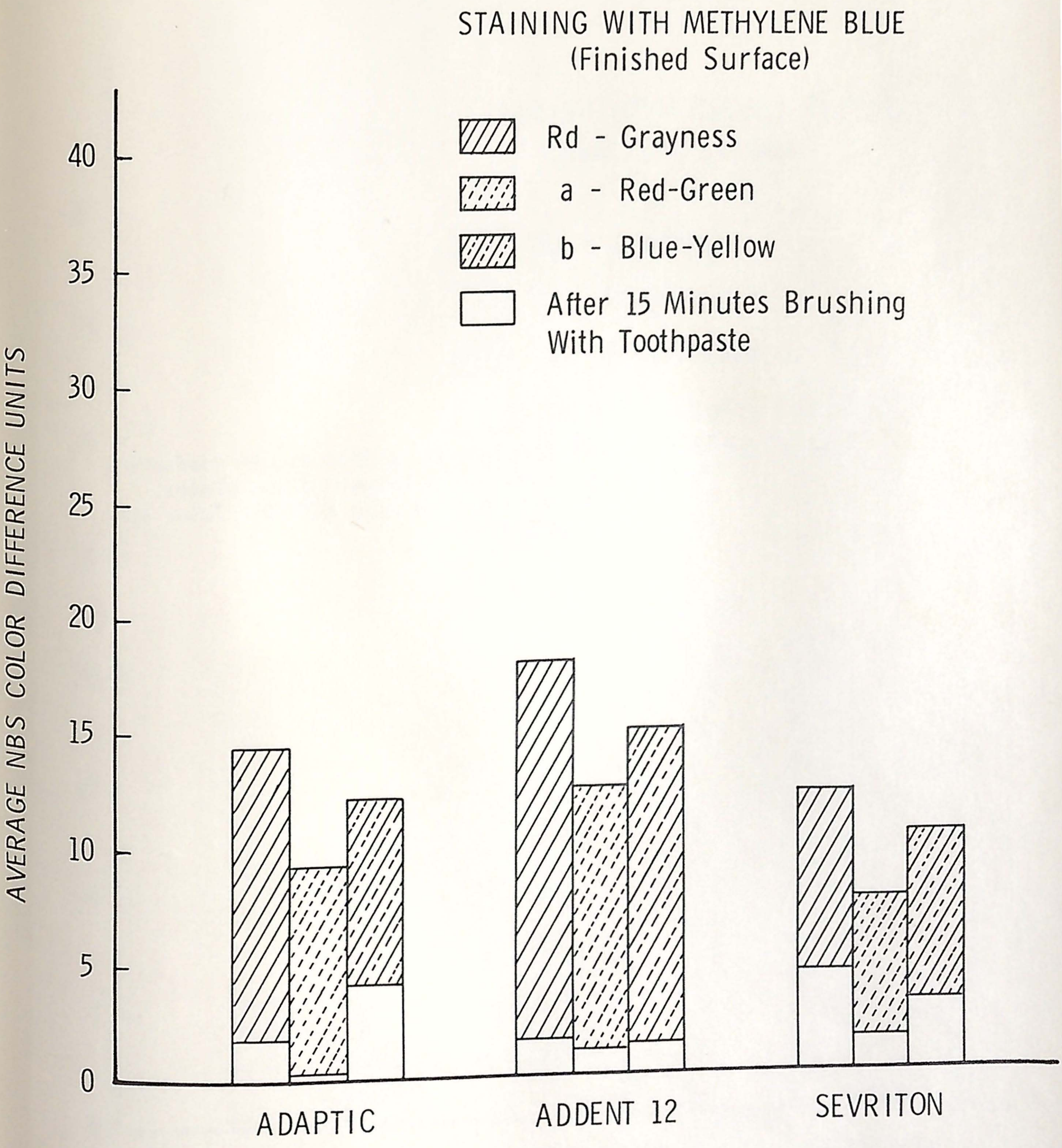
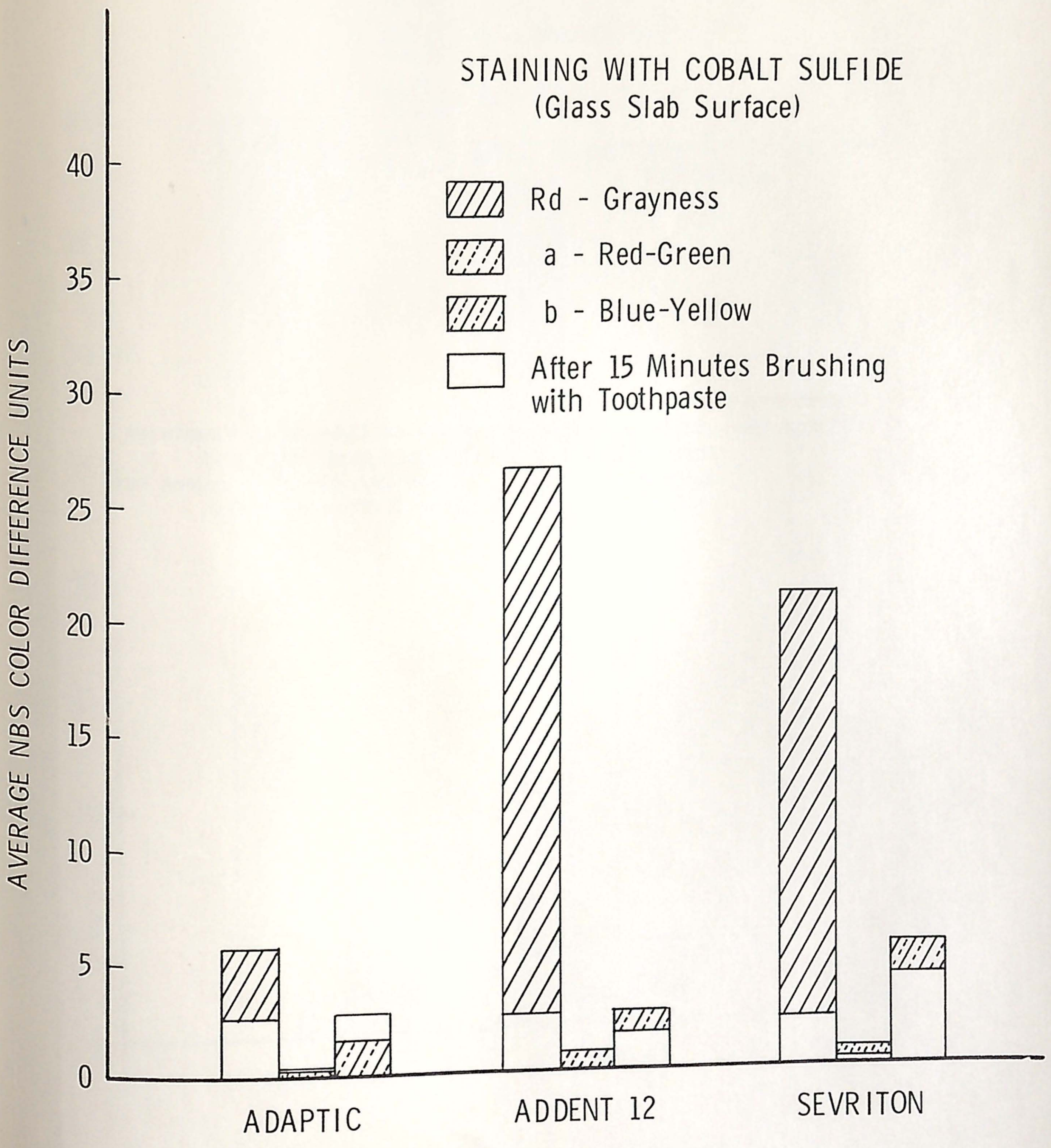

STAINING WITH METHYLENE BLUE
(Finished Surface)
Rd - Grayness
a - Red-Green
b - Blue-Yellow
After 15 Minutes Brushing With Toothpaste
AVERAGE NBS COLOR DIFFERENCE UNITS
40
35
30
25
20
15
10
5
0
ADAPTIC
ADDENT 12
SEVRITON

Figure 11: Stain produced by cobalt sulfide on the surfaces of resin specimens cured between glass plates. Color change was measured with a Hunter Color and Color Difference Meter.



STAINING WITH COBALT SULFIDE
(Glass Slab Surface)
Rd - Grayness
a - Red-Green
b - Blue-Yellow
After 15 Minutes Brushing with Toothpaste
AVERAGE NBS COLOR DIFFERENCE UNITS
0
5
10
15
20
25
30
35
40
ADAPTIC
ADDENT 12
SEVRITON

Figure 12: Stain produced by cobalt sulfide on the surfaces of resin specimens finished with 400A grit carborundum paper. Color change was measured with a Hunter Color and Color Difference Meter.

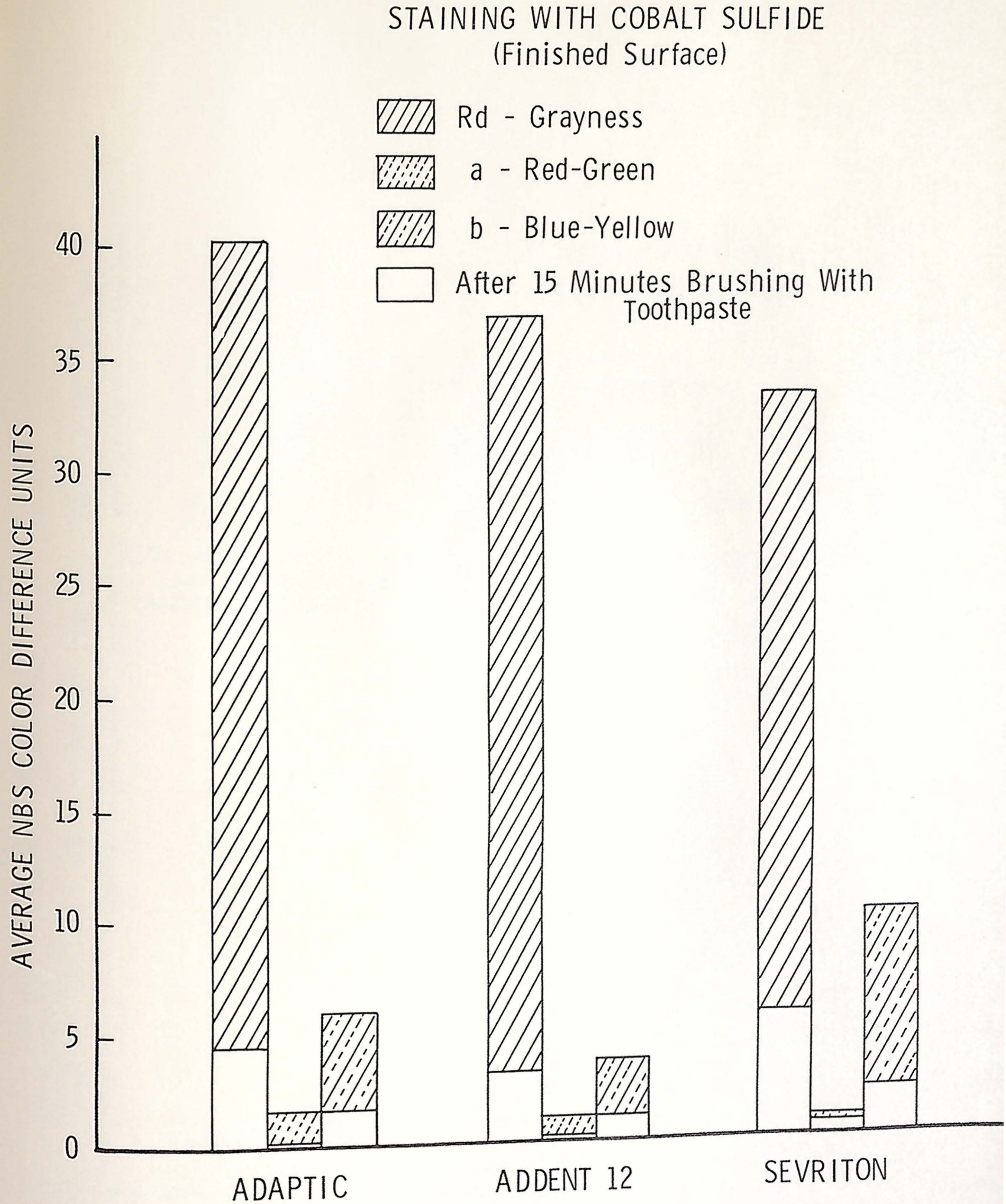

STAINING WITH COBALT SULFIDE
(Finished Surface)
Rd - Grayness
a - Red-Green
b - Blue-Yellow
After 15 Minutes Brushing With Toothpaste
AVERAGE NBS COLOR DIFFERENCE UNITS
40
35
30
25
20
15
10
5
0
ADAPTIC
ADDENT 12
SEVRITON

Figure 13: Stain produced by lipstick on the surfaces of resin specimens cured between glass plates. Color change was measured with a Hunter Color and Color Difference Meter.

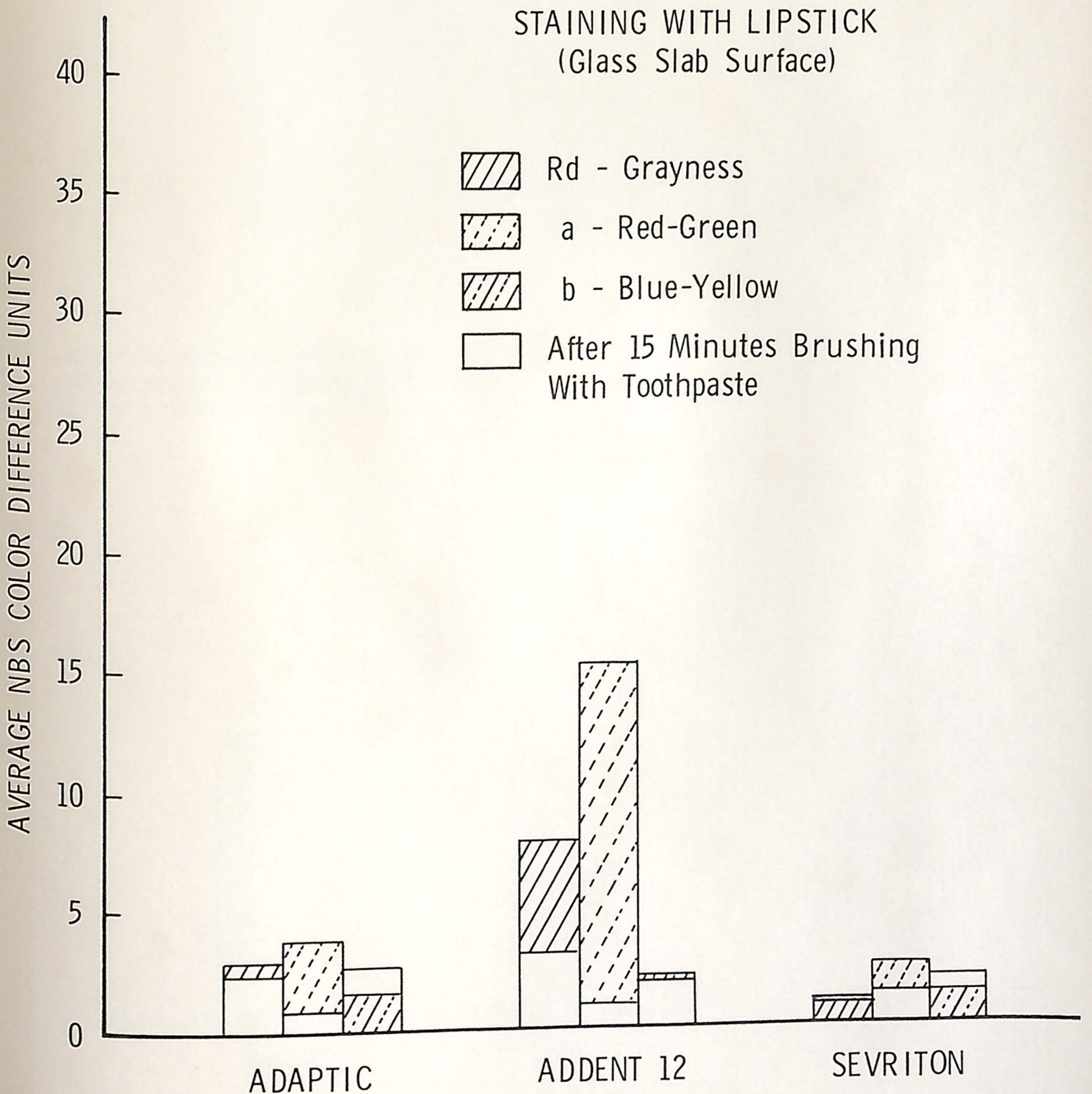

STAINING WITH LIPSTICK
(Glass Slab Surface)
Rd - Grayness
a - Red-Green
b - Blue-Yellow
After 15 Minutes Brushing With Toothpaste
AVERAGE NBS COLOR DIFFERENCE UNITS
0
5
10
15
20
25
30
35
40
ADAPTIC
ADDENT 12
SEVRITON

Figure 14: Stain produced by lipstick on the surfaces of resin specimens finished with 400A grit carborundum paper. Color change was measured with a Hunter Color and Color Difference Meter.

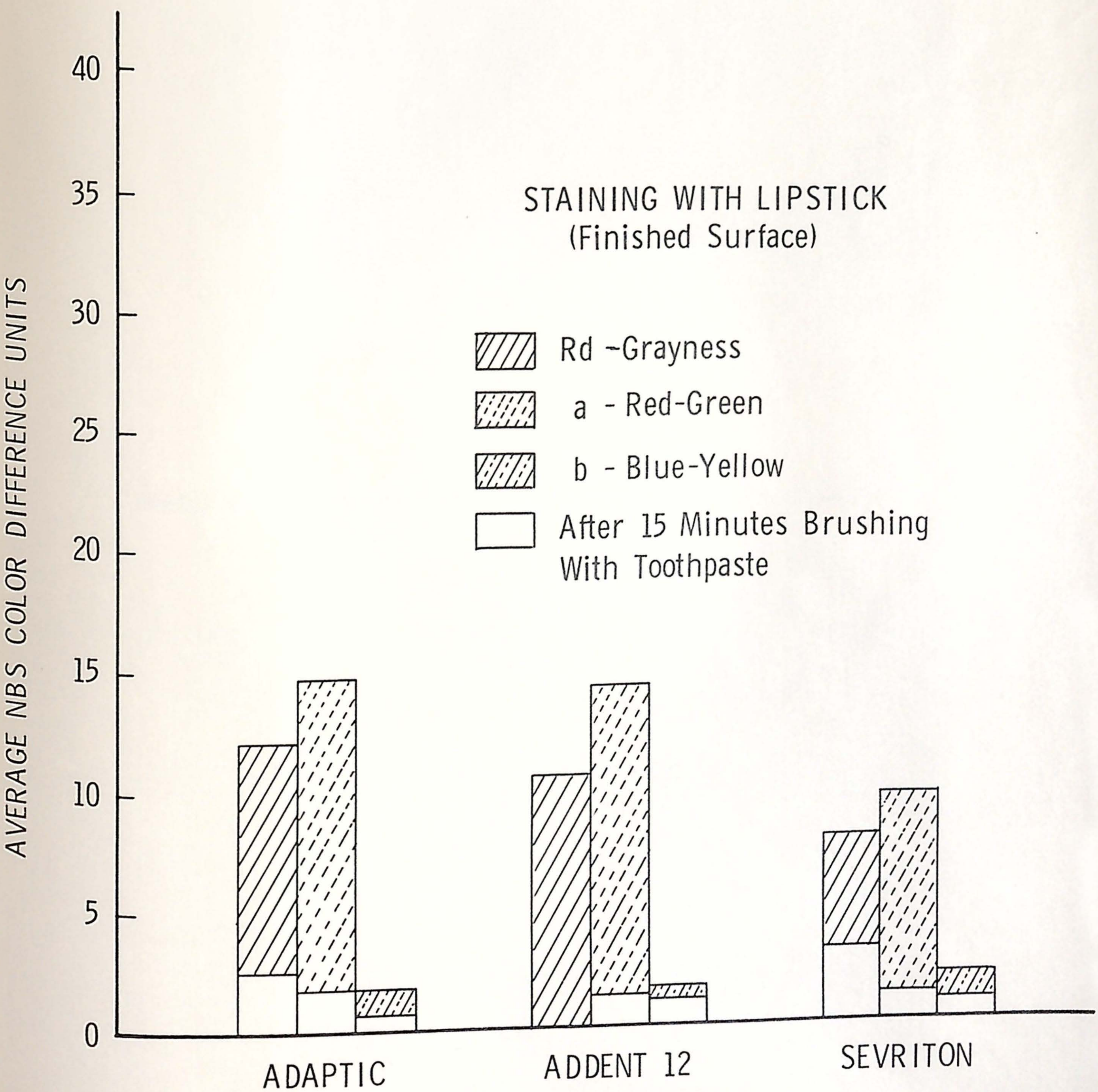

STAINING WITH LIPSTICK
(Finished Surface)
Rd -Grayness
a - Red-Green
b - Blue-Yellow
After 15 Minutes Brushing With Toothpaste
AVERAGE NBS COLOR DIFFERENCE UNITS
40
35
30
25
20
15
10
5
0
ADAPTIC
ADDENT 12
SEVRITON

Figure 15: Photograph of stained, unbrushed specimens (glass slab finish). The products are:

A. Adaptic
B. Addent 12
C. Sevriton

The staining media are:

1. control (unstained)
2. methylene blue
3. cobalt sulfide
4. lipstick

Figure 16: Photograph of stained, brushed specimens (glass slab finish). The products are:

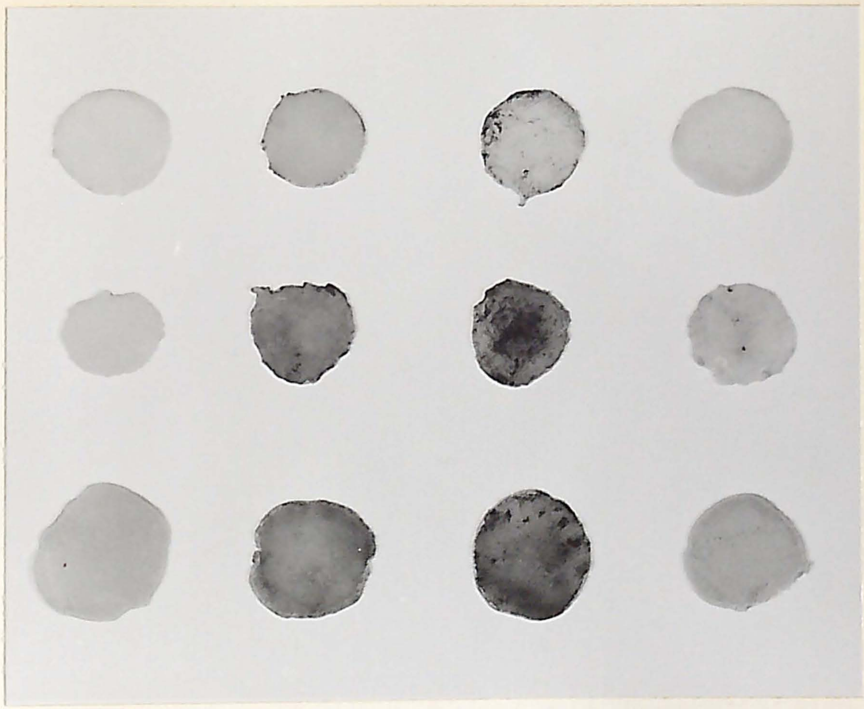
D. Adaptic
E. Addent 12
F. Sevriton

The staining media are:

1. control (unstained)
2. methylene blue
3. cobalt sulfide
4. lipstick

1 2 3 4

A
B
C



1 2 3 4

D
E
F

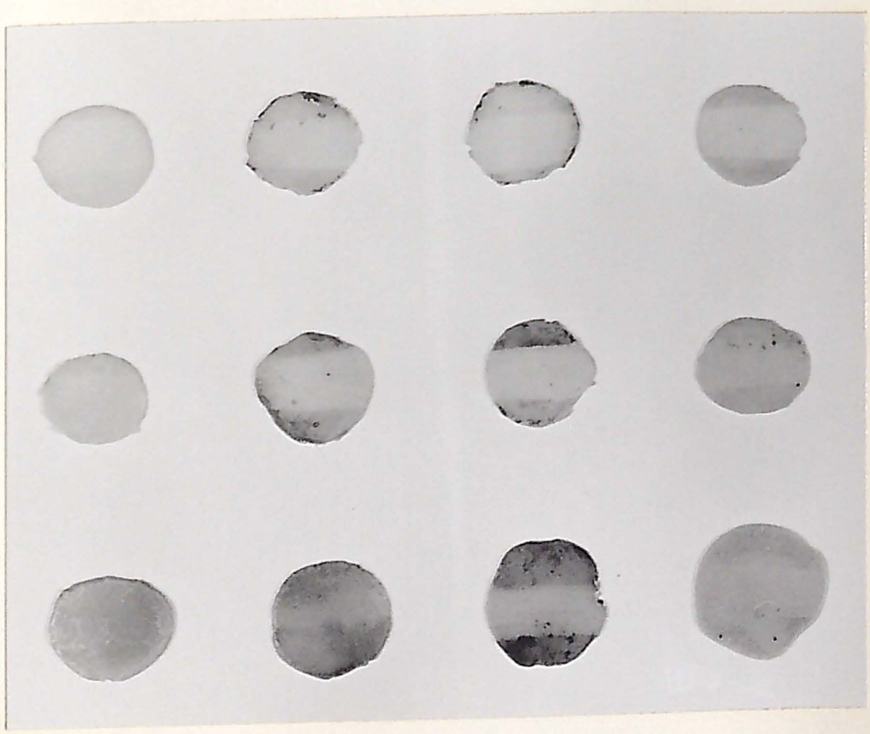


Figure 17: Photograph of stained, unbrushed specimens (finished with 400A grit paper). The products are:

A. Adaptic
B. Addent 12
C. Sevriton

The staining media are:

1. control (unstained)
2. methylene blue
3. cobalt sulfide
4. lipstick

Figure 18: Photograph of stained, brushed specimens (finished with 400A grit paper). The products are:

D. Adaptic
E. Addent 12
F. Sevriton

The staining media are:

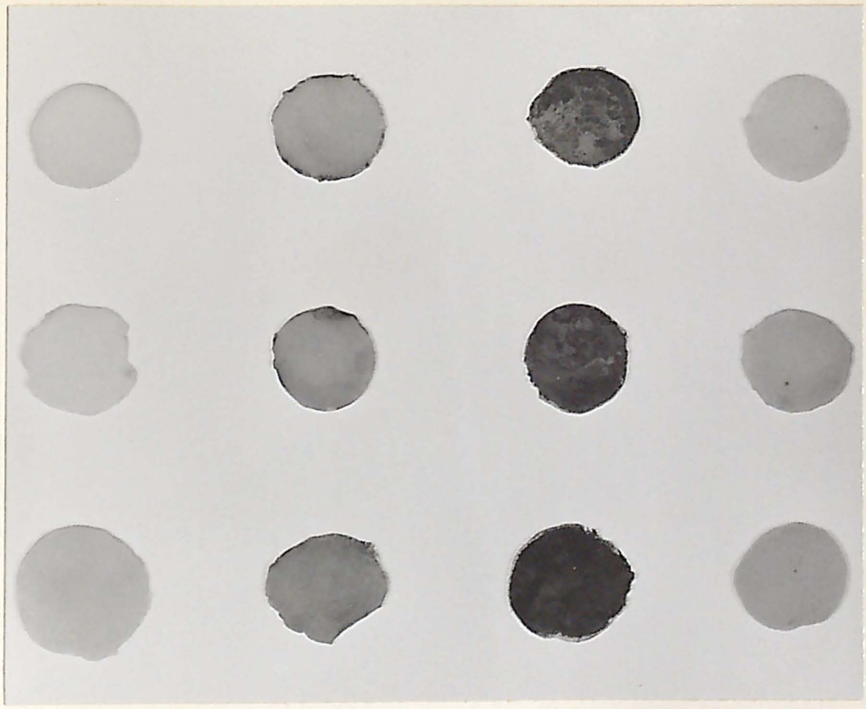
1. control (unstained)
2. methylene blue
3. cobalt sulfide
4. lipstick

1 2 3 4

A

B

C



1 2 3 4

D

E

F

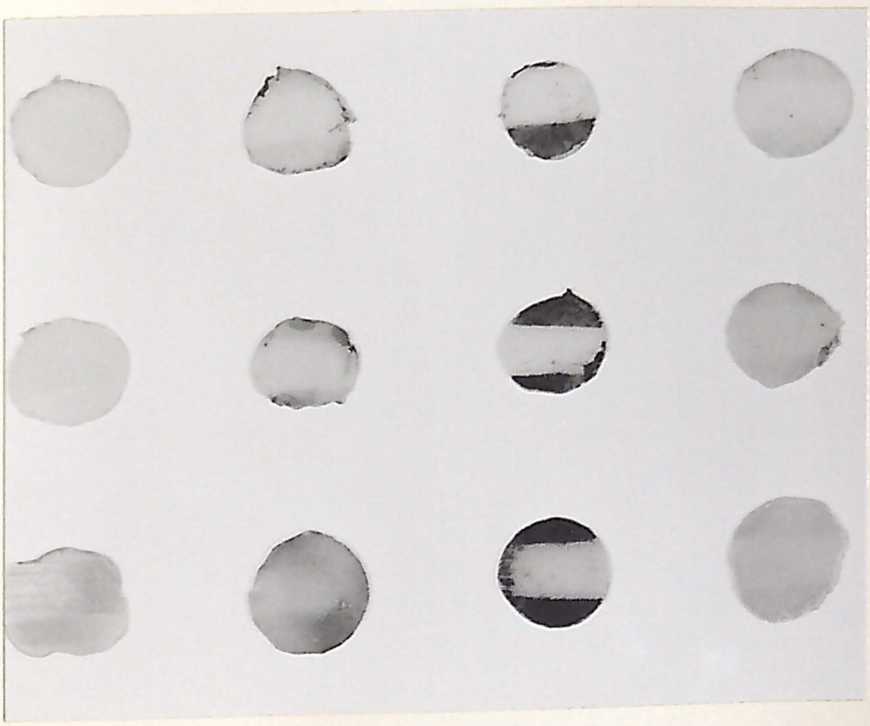
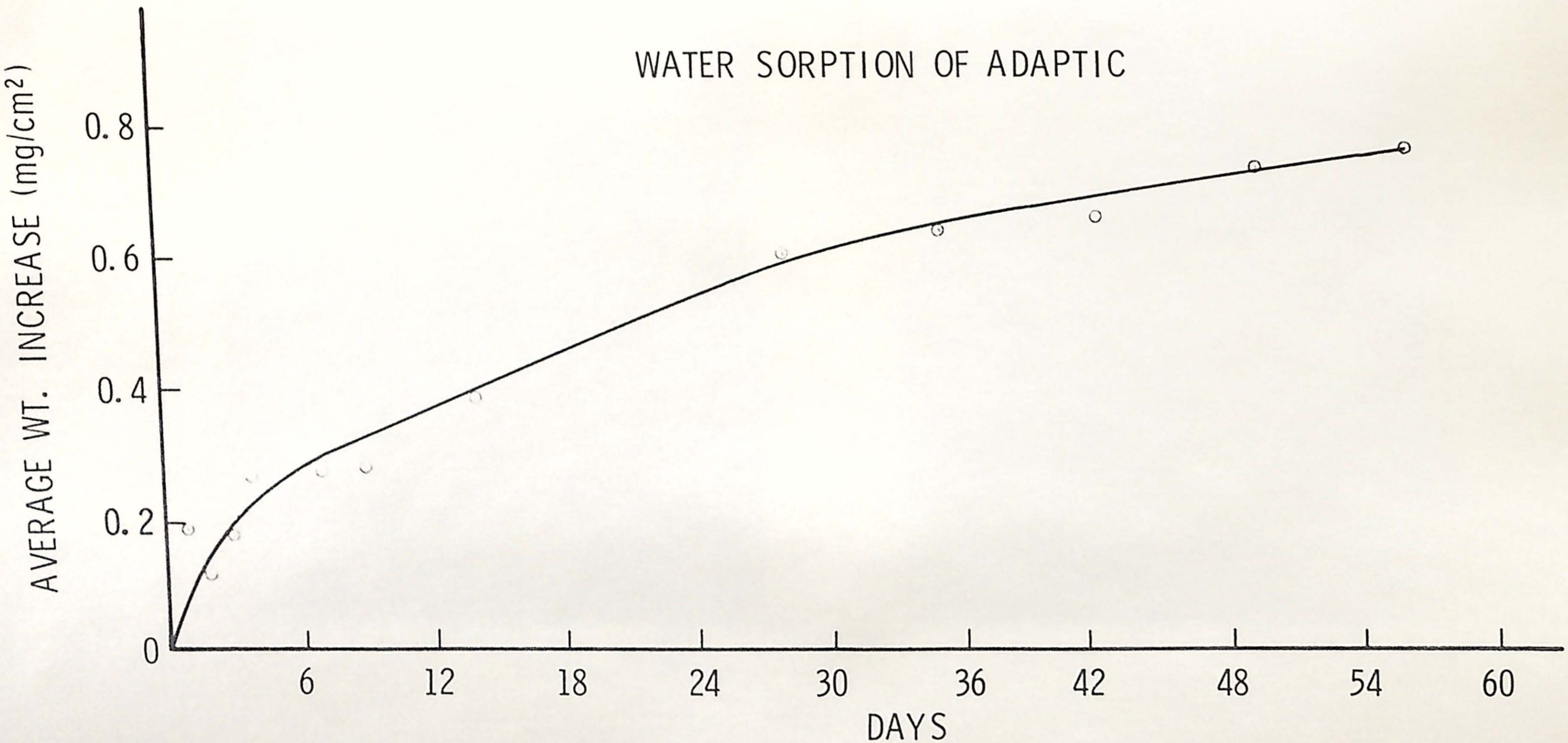


Figure 19: Water sorption of Adaptic measured for 56 days.



WATER SORPTION OF ADAPTIC
AVERAGE WT. INCREASE (mg/cm²)
0.8
0.6
0.4
0.2
0
6
12
18
24
30
36
42
48
54
60
DAYS

Figure 20: Photograph of paired test restorations taken immediately after polishing the control restoration. The maxillary second bicuspid has been restored with a DO Velvalloy amalgam and the adjacent first molar has been restored with an MO Adaptic.

Figure 21: Photograph of an MOD Adaptic restoration in a mandibular first permanent molar. This is one restoration of a test pair which was placed when the clinical study was initiated.

Figure 22: Photograph of paired restorations taken one year after placement. The DO Adaptic in the maxillary first bicuspid exhibits proximal discoloration which was sometimes seen. The quality of the adjacent MO Velvalloy restoration is as good as any that were observed at the one-year evaluation.

Figure 23: Photograph of another pair of test restorations which were examined at the one-year evaluation. The DO Adaptic restoration exhibits considerable discoloration where it is in close proximity with the MOD Velvalloy restoration. Even marginal discoloration in the area is evident.

Figure 24: Large MO Adaptic restoration in a maxillary first permanent molar as observed at the one-year evaluation. The rough appearance of the surface is characteristic for this material.

Figure 25: An MOD Adaptic restoration in a mandibular second bicuspid paired with and compared to a DO Velvalloy restoration after one year. The slight marginal breakdown seen with the amalgam was not observed with the composite material.

Figure 26: Another pair of test restorations which were evaluated after one year. The DO Velvalloy in the maxillary first bicuspid exhibits marginal breakdown which is often seen in amalgam restorations, but generally is of no clinical significance. The esthetic qualities of the DO Adaptic in the adjacent bicuspid are obvious.

DISCUSSION

PART I - LABORATORY STUDY

A. Abrasion Resistance and B. Hardness

There is often a direct relationship between abrasion resistance of a given material and its hardness. Generally, the harder a material is, the more resistant it is to abrasion. This rule also applies to the abrasives themselves. When all other things are equal (particle size, shape, etc.), the harder the particles, the greater are their abrasiveness.[12]

However, this relationship may not apply when different types of materials are compared. For example, at 24 hours Adaptic is four times more resistant to abrasion than Velvalloy, with a toothbrush and flour of pumice, yet the amalgam exhibits a 24-hour surface hardness twice that of Adaptic.

When one considers the structural components of Adaptic, this phenomenon can possibly be understood. The resin portion of Adaptic no doubt has much the same physical properties as those of most other unfilled dental resins (KHN less than 20, and little resistance to abrasion). However, the alpha quartz filler has markedly different properties (KHN over 800 and correspondingly more resistant to abrasion).[66] These filler particles are initially bound securely to the resin matrix. Therefore, when the Knoop diamond indenter is used to measure the surface hardness of the material, the small quartz particles are cushioned by the resin matrix and easily displaced by the indenter. The hardness values obtained would then more nearly reflect those of the resin material rather than the quartz.

On the other hand, when the abrasion resistant properties of Adaptic are considered, the quartz particles become more significant. These small, irregular, hard particles are very abrasive themselves and they afford a great deal of protection to the composite material. The effect of these filler particles is particularly important when they are present in the high concentrations used in Adaptic. Even though the resin binder is readily abraded away wherever it is exposed on the surface, the deeper layers still retain the quartz particles which are densely packed in the material. Therefore the abrasion resistance of Adaptic, when tested with the laboratory brushing machine, more nearly reflects the resistance of the quartz filler rather than the resin.

On the basis of the physical properties, abrasion resistance may well be the most impressive one that Adaptic possesses. It should be investigated in much more detail with a variety of abrasives. It is hoped that the clinical investigation now underway will provide some insight into its ability to withstand normal physiologic wear in the oral cavity. The matter will be discussed later in this section.

C. Marginal Leakage

Based on the test employed in this study, the adaptation of Adaptic to cavity margins and walls seems quite acceptable. Results of the microleakage tests for Adaptic compared favorably with results reported for other acrylic resin and composite restoratives which have been similarly evaluated.[32,38-40,56,57,67] In some instances the results were superior. However, none of these previous studies included Adaptic in the evaluations.

Adaptic does not require a cavity primer or liner prior to its placement, as do some other products to improve their seal, yet the material exhibited adequate sealing capability. The efficacy of the seal of the Adaptic restorations did not significantly diminish with increased storage time, as has been observed with other resin materials.[32] Despite the thick and tacky consistency of the material during its placement into a cavity, it apparently can adapt very closely to the cavity walls.

The excellent marginal seal provided by amalgam has long been established by in vitro and in vivo testing. The application of a cavity varnish to cavity walls prior to the placement of amalgam has also been shown to improve the initial seal of the material.[56,57] As expected in this study, the Velvalloy restorations placed over the cavity varnish exhibited an excellent seal at all testing intervals.

When the test restorations were subjected to temperature variation for an extended period, the marginal integrity for both the Adaptic and the Velvalloy restorations degenerated. It seems reasonable to anticipate increased leakage under the rigorous conditions of the test employed. The increased leakage around both materials seemed to be proportional; however, the Velvalloy restorations remained superior to the Adaptic restorations but the relative difference between the materials was approximately the same as the differences observed in the initial leakage tests. This observation should not be surprising since the coefficients of thermal expansion for these materials are nearly equal. The question of the clinical significance of these differences still remains.

D. Strength

It has been reported that a satisfactory amalgam should have an ultimate compressive strength of at least 45,000 pounds per square inch.[12] One cannot use this figure as an absolute requirement for all posterior restorative materials because a compatible combination of a number of properties is required for a clinically satisfactory restoration. The compressive strength of Adaptic is less than amalgam; however, it is a totally different system and it may therefore have somewhat different strength requirements. The question to be answered about the material is not how strong it is, but whether it is strong enough to adequately serve as a posterior restorative material. This question can be resolved only by a long term clinical investigation.

E. Color Stability

The test employed for color stability obviously would not apply to amalgam. Even for Adaptic the test is at best a subjective evaluation, relying totally on the visual perception of color change by the examiners. It is noteworthy, however, that all seven examiners agreed that any color change which may have occurred during the test was negligible. Thus Adaptic passed the test for color stability outlined by the American Dental Association. This should not imply that the material would remain color-stable in the oral environment; but had the test shown the material to have color instability, the material would probably also exhibit color change clinically. It should be remembered that this test evaluates only color shift within the material, not surface stain, as is discussed in the next section.

F. Staining Characteristics

No exact correlation has been shown to exist between the in vitro staining tests employed in this study and susceptibility of a material to clinical stain. Nevertheless, these tests provide a means of comparing materials under a given set of controlled conditions and thereby give some insight as to the relative susceptibility of materials to various stains.

The amount of stain picked up by all of the test materials was greater on the "finished" surfaces than on the "glass slab" surfaces. It seems reasonable that stain susceptibility increases as surface roughness increases.

All stains tested could be effectively removed from the specimen surfaces with a toothbrush and toothpaste. Further evidence indicates that cleansing the specimens with a toothbrush and toothpaste causes no significant wear on the surfaces of the composite materials. Thus the clinical significance of the surface susceptibility of stains on composite materials may therefore be relatively unimportant in patients who practice good oral hygiene. However, no attempt was made to remove the surface stain in the clinical restorations to establish the efficacy of this technic.

G. Water Sorption

The water sorption data for Adaptic for a 56 day period indicate that the material continues to sorb water at an extremely slow rate and did not reach equilibrium in that time interval. This finding is inconsistent with the work of Lee, Swartz,and Smith.[36] Their tests indicated that Adaptic essentially reached equilibrium in approximately four days. However, Peterson, Phillips, and Swartz[32] have reported data for another composite material, Addent, which showed a continual slow rate of water sorption for 200 days without reaching equilibrium. That finding also conflicts with Lee, Swartz, and Smith[36] since their data for Addent showed water equilibrium in about four days.

It would appear that the behavior of composite materials with regard to water sorption has not yet been adequately defined. Further tests are indicated. The true clinical significance of slow, continual sorption by these materials is unknown. If sorption continues indefinitely, it could ultimately have a deleterious effect on the seal of the restoration and a reduction in certain physical properties.

H. Mercury Content

Nadal, Phillips, and Swartz[4,5] have shown that desirable clinical properties of amalgam degenerate significantly if the residual mercury content exceeds 55 per cent. They also reported that the strength of amalgam remains rather constant when the residual mercury content ranges between 45 and 55 per cent.

The residual mercury content of various Velvalloy samples ranged between 45 and 50 per cent. Since mercury content was measured for specimens representative of all types of samples used in this investigation, one would expect that the Velvalloy specimens were capable of maximum performance.

PART II - CLINICAL STUDY

The changes in anatomic form, at one year, of a few of the Adaptic restorations are noteworthy. Apparently these changes were due to occlusal wear resulting in loss of material in the marginal ridge areas. This phenomenon was not observed in the amalgam restoration. Although the occlusal wear of the composite material was slight and apparently of little clinical significance, it certainly could become quite significant over the expected lifetime of a restoration if the wear continues.

The in vitro abrasion tests conducted with toothbrushes and flour of pumice slurries indicated that Adaptic was considerably more wear resistant than amalgam. Thus this particular test does not appear to be valid for predicting the relative wear properties of these two materials in Class II restorations even though the test may still be reliable for evaluating resistance to toothbrush abrasion. The relationship between the properties of hardness and abrasion resistance has already been pointed out. Of interest here is the fact that in vitro hardness tests on 24-hour specimens showed Velvalloy amalgam to have approximately twice the hardness of Adaptic. Perhaps surface hardness of a material is a more reliable indicator of resistance to occlusal wear in vivo.

The composite resin restorations earned a superior clinical rating for marginal adaptation. However, it is difficult to explain why this occurred. It might be easier to identify those properties which are not apparently closely identified with loss of marginal integrity rather than those properties which encourage it. It appears, for example, certain strength properties do not play a major role in maintaining marginal adaptation. The marginal integrity of the amalgam restorations, as compared to the Adaptic restorations degenerated significantly during the year, yet the amalgam had considerably greater 24-hour compressive and tensile strengths than the composite resin. Brittleness (i.e. ductility) might also be a property worthy of consideration because brittle materials would be likely to fracture in thin marginal areas. Although no specific tests for brittleness were carried out on the materials, the nature of the break of the strength specimens (loud noise, floor trembled, "clean" fractures, and apparent release of energy abruptly) seemed to indicate that the brittleness of Adaptic was equal to or exceeded that of the amalgam. If this is true, then brittleness per se is not solely responsible for marginal fractures. The marginal discrepancies observed in the amalgam restorations (excluding the three which were fractured through the bulk of the material) were the classical "ditching" defects which seem inherent to nearly all amalgam restorations. The chemical effects of the oral environment on these two materials (although they were not investigated in this study) may possibly be a factor. Electrochemical corrosion has been postulated as an important underlying cause for marginal breakdown in amalgams,[12] but this kind of degradation would not be expected in composite resins. The flow properties as well as the more recently identified properties of "dynamic creep" may also play a role in marginal degeneration of amalgam restorations.[68]

The color changes of the composite restorations which occurred during the year appeared to result from surface stain collection. This was true for both color match changes and marginal staining. Since there appeared to be no deep color changes in the material, the in vitro color stability tests which were carried out may still have validity. Tests for staining characteristics on Adaptic showed that surface roughness may play an important role in the material's susceptibility to cobalt sulfide stain, since the "finished" surfaces were much more susceptible to the stain than the "glass slab" surfaces. These stains would readily brush away with toothpaste and toothbrush. Since the discolorations on the surfaces of the clinical restorations appeared as dark, often greyish stains along the margins and proximal surfaces not readily accessible to a toothbrush, it is possible that the intra-oral sulfides are responsible for this phenomenon. The in vitro marginal leakage tests also support the clinical observation that the cavo-surface marginal discoloration was only superficial.

Further discussion will be more meaningful after the results of a longer clinical observation period are known. The overall clinical performance of one material has not been shown to be superior to the other after one year. Both materials have performed satisfactorily as posterior restoratives thus far in the study. Meticulous technics and optimum clinical conditions were maintained for all the teeth when they were prepared and restored, the clinical performance of these materials could have been considerably different if they had been placed under less desirable conditions. It is important to realize that the testing period to date has been short and that the long-term relative performance of these materials is yet to be assessed.

SUMMARY AND CONCLUSIONS

The design and initial results have been reported of a continuing long-term study comparing the clinical performance of two restorative materials, a representative composite resin and amalgam, in Class II restorations. A total of 124 pairs of Class II restorations were placed in the permanent teeth of 73 patients. The base line evaluation was conducted within two months after the initial placement of the paired restorations. At the base line examination 88 per cent (109 pairs) of the original restorations were evaluated and of this group 84 per cent (92 pairs) were evaluated one year later. The teeth and their restorations were clinically examined for color match, cavo-surface marginal discoloration, anatomic form, marginal adaptation, and caries.

Certain laboratory tests were conducted on the materials in order to identify their properties. It was hoped that the data collected would lead to a better understanding of the clinical behavior of the respective materials.

The composite resin, Adaptic, was found to be four times more resistant to toothbrush abrasion than the amalgam, Velvalloy, in a slurry of flour of pumice. However, loss of material due to wear was observed clinically only on the Adaptic restorations.

The Knoop surface hardness of 24-hour laboratory specimens showed Velvalloy to be approximately 97 while Adaptic was only 49. These data might indicate that surface hardness is a more reliable test of in vivo wear resistance of posterior restorations than the measurement of resistance to toothbrush abrasion.

The results of marginal microleakage tests conducted on both materials were consistently good. Velvalloy with Copalite was slightly superior to Adaptic in all test groups, but the tests indicated that both materials should be acceptable cavity sealants. Even under severe thermocycle testing, both materials maintained relatively good marginal integrity.

In one hour, Adaptic reached 88 per cent of its compressive strength at one month and 66 per cent of its one-month tensile strength. The one-hour Velvalloy strengths were 28 per cent and 30 per cent of its one-month strengths for the same two properties. Although early strength of Adaptic is considerably superior to that of amalgam, Velvalloy is significantly stronger than Adaptic at 24 hours. Varying the Catalyst paste/Universal paste ratio of Adaptic from 1.0/2.0 to 2.0/1.0 has no appreciable effect on the compressive strength of the material.

Adaptic passed the American Dental Association in vitro color stability test for denture base resins, but a significant color shift was observed clinically at the end of the first year. Since the color changes noted appeared to be due to surface stain, the in vitro tests would not likely be indicative of these types of discoloration.

The "finished" surfaces of Adaptic showed an affinity to in vitro cobalt sulfide stain. It was found that this stain could be readily removed from the surface with a toothbrush and toothpaste. Perhaps the dark surface stains observed clinically on the one-year restorations were related to this apparent sulfide affinity of the material. The stains were found primarily on proximal surfaces - areas not readily accessible to the toothbrush.

The solubility of Adaptic in both glass distilled water and 0.001M citric acid was negligible. The water sorption of Adaptic was at a slow rate, but equilibrium had not yet been reached when the tests terminated at the end of 56 days. This property and its clinical significance have not yet been adequately explored for composite resin materials.

The results of the clinical study at the end of one year have not shown either of the two materials tested to be significantly superior over the other as a Class II restorative material, although the following findings were considered important.

1. No recurrent caries were found around any of the restorations.
2. The amalgam restorations were superior for maintenance of anatomic form.
3. The composite restorations exhibited superior marginal adaptation.
4. All composite resin restorations were intact but three amalgam restorations were fractured through the bulk of the material.
5. There were a significant number of composite restorations showing slight color changes.
6. Cavo-surface marginal discoloration of the composite resins also increased considerably but the stains were always superficial.

The performance of each was considered to be clinically successful even though the physical properties were not always comparable for the two materials. No exact relationship was established for these properties and clinical performance. It is to be emphasized that the clinical testing period has not yet been adequate to permit any definite conclusions about the comparative clinical durability of the test restorations.

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ABSTRACT

A Composite Resin Versus an Amalgam: A Study of Certain Properties and the Design and Initiation of a Clinical Investigation

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Certain properties of a representative composite material were evaluated by in vitro testing and compared to those of other types of restorative materials. A clinical study designed to evaluate the performance of the composite material as compared to amalgam for Class II restorations was initiated and one-year results are reported.

Laboratory tests for abrasion resistance, hardness, marginal leakage, strength, color stability, staining characteristics, solubility, and water sorption were conducted.

The clinical study is still in progress but the results after one year indicated that the composite resin test restorations, as well as the amalgam control restorations, were generally satisfactory. In overall clinical performance neither material was superior to the other. The amalgam restorations received a superior rating for anatomic form while the composite restorations were superior in terms of marginal adaptation. No clinical evidence of recurrent caries, associated with any of the restorations, was detected. Surface discoloration was a significant finding on the composite restorations, but it was confined to proximal areas and may be related to the difficulty of cleaning these areas with a toothbrush.

No conclusions can yet be made regarding the long-term clinical performance of the composite resin used in this investigation as a Class II restorative material.